



LONG-RANGE RESEARCH INITIATIVE

Global Research Strategy

ADVANCING CHEMICAL SAFETY ASSESSMENT FOR THE 21ST CENTURY



AROUND THE WORLD, THE CHEMICAL INDUSTRY
CURRENTLY FACES MULTIPLE CHALLENGES.
SOUND SCIENCE IS ESSENTIAL FOR
ADDRESSING THESE CHALLENGES AND FOR
PROVIDING THE BASIS FOR DECISION MAKING
ABOUT CHEMICAL SAFETY AND INNOVATION.



LRI MISSION — LINKING RESEARCH TO PRACTICE AND POLICY

The mission of the LRI is to advance approaches for the scientific assessment of the safety of chemicals and to improve our understanding of the potential health and environmental risks. By fostering innovative research, we implement critical initiatives that improve the information needed for science-based decision making, build inter-disciplinary and international scientific networks, and engage with partners around the world to link research to practice and policy. The LRI program is tailored to adapt to changing issues in chemical safety assessment, to improve consumer confidence in our products, and to support our goal to be the leader in chemical safety assessment research.

SINCE 1999, the International Council of Chemical Associations' (ICCA) Long-Range Research Initiative (LRI) has supported high quality scientific research to address the demands of decision makers and the public to better understand the potential impacts 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 three regional LRI research programs support complementary areas of research that target the science-policy interface to improve chemical safety and reduce uncertainty.

Looking to the future, the growth of the chemical industry in the Middle East, Asia, South America, and Africa during the past decade increases the potential for broader global participation in the mission of the LRI program.



Global Challenges to the Chemical Industry

IMPLEMENTATION OF Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) in the European Union (EU) and of the Chemical Substances Control Law (CSCL) in Japan...reform of the Toxic Substances Control Act (TSCA) in the United States...the industry's obligations under the Strategic Approach to International Chemicals Management (SAICM)... uncertainty regarding public acceptance of innovation from the chemical industry...de-selection pressures for chemicals.

Around the world, these activities are the basis for demands from industry's product stewards, those in governmental and regulatory agencies, and the general public for high-quality scientific information about the potential health and environmental risks from chemicals. These global activities also highlight the critical need to advance chemical safety assessment and the importance of the chemical industry's investment in the LRI. The LRI provides the industry with innovative approaches to address challenging issues that include:

PREMATURE USE OF NEW CHEMICAL TESTING DATA

Recent developments in chemical testing technologies provide powerful tools that can rapidly generate large volumes of hazard data for chemicals. Interpreting these data to better understand the potential health and environmental impacts of chemicals remains a challenge. Premature use of these data by regulatory agencies and non-governmental organizations to characterize and prioritize chemicals could result in the development of regulations and policies with significant economic costs yet uncertain human health and environmental benefits.

NEED FOR MORE EXPOSURE DATA FOR CHEMICALS CURRENTLY IN COMMERCE

Meaningful assessment of potential health and environmental risks from chemicals requires not only hazard information but also information about environmentally-relevant exposures to chemicals. Making decisions about potential risks without exposure data can result in unwarranted responses, such as product labeling and product de-selection.

INCREASED PUBLIC DEMANDS FOR SAFE PRODUCTS

Consumers are concerned about potential health risks from chemical exposures that can occur in everyday life at home, at work, and outdoors. Media reports linking chemicals detected in the body to potential health effects have produced demands from the public for more information about product safety. A lack of sound scientific information about product safety can undermine public confidence in our products and may prompt restrictions in their use or their removal from the marketplace.

CONCERNS ABOUT ANIMAL WELFARE

Without innovative approaches that can reduce the need for animal testing, the chemical industry will continue to face concerns about animal welfare. In addition, use of current animal testing procedures prolongs processes for research and development and product safety evaluations as well as delays time to market for new products.





Global Research Strategy

THIS LRI GLOBAL RESEARCH STRATEGY is designed to directly address the current challenges faced by the industry as it advocates for decision making about chemicals based on sound science. This strategy, Advancing Chemical Safety Assessment for the 21st Century, targets the science-policy interface to improve chemical management and innovation assessments.

The strategy comprises three priority research areas that were mutually identified by the LRI regional programs as key for addressing the global challenges:

- Innovating Chemical Testing
- Understanding Everyday Exposures to Chemicals
- ▶ Translating Research Outcomes for Product Safety

These three priority research areas and their value to the chemical industry will be described in more detail in the pages that follow.

OUR PRINCIPLES

SCIENTIFIC EXCELLENCE.

The best research proposals and most qualified scientists will be selected for funding.

TRANSPARENCY. Research will be conducted openly, and the results will be publicly available.

Science in Action

THROUGH THE ICCA, the three regional LRI programs share common objectives, information, and experiences, while also targeting research on topics that meet the industry policies and priorities within each region. This approach ensures that the LRI research programs and projects among the Cefic, ACC, and JCIA are complementary without duplication and maximizes industry's return on investment. These LRI programs also support the objectives of Responsible Care®, the chemical industry's global voluntary commitment to continuous improvement in environmental, health, safety, and security performance.

The goals of the LRI are to:

- Coordinate research among the three LRI programs to advance approaches for chemical safety assessment
- Support informed decision making and risk management decisions by increasing scientific knowledge through research
- Extend information worldwide on the health, safety, and environmental impacts of the chemical industry's products and processes in dialogue with the scientific and regulatory communities



FAIR AND UNBIASED CONDUCT. Potential conflicts of interest will be rigorously evaluated.

RELEVANCE TO THE CHEMICAL INDUSTRY. Research will address priority issues of the chemical industry regarding the health and environmental impacts of chemicals.



Innovating Chemical Testing

LRI research develops tools to:

- Increase efficiencies for chemical testing and reduce animal use
- ▶ Advance approaches for interpreting the data from chemical testing
- ▶ Meet regulatory and industry data requirements



LRI research develops tools and approaches that can reduce chemical testing costs, time, and animal use as well as facilitate meeting regulatory data requirements. These tools also have the potential to expedite design of new materials, products, and chemical solutions.

RESEARCH OBJECTIVES

- New research tools, such as high-throughput in vitro assays and genomics, present exciting approaches that have the potential to link information at the molecular level to health and environmental impacts and to revolutionize chemical safety assessment.
- LRI research advances development of innovative tools to provide critical data for robust evaluations of chemicals and new technologies, such as nanotechnology, and advances replacement of traditional chemical testing methods that use animals.
- LRI research promotes **proper** application of the new tools and appropriate interpretation of the data to avoid identification of hazardous but risk irrelevant properties of chemicals and increases public acceptance of new processes and products.



Understanding Everyday Exposures to Chemicals

LRI research provides approaches to:

- Inform meaningful decisions about potential risks from chemical use
- Generate data regarding environmentally-relevant exposures to chemicals
- Advance development of efficient product and process design



VALUE TO THE CHEMICAL INDUSTRY

LRI exposure research can provide the critical information link for appropriately assessing the potential health and environmental risks from chemicals; this approach can decrease the likelihood of decisions based on hazard data alone. Predictive models offer potential resources to efficiently and cost-effectively generate estimates for consumer exposures and to address current exposure data gaps for the majority of chemicals in commerce.

RESEARCH OBJECTIVES

- Information about exposures to chemicals is critical for assessing potential human and environmental health risks and for informing decisions about efficient design of new chemicals.
- LRI research in exposure science fosters initiatives to develop predictive models for estimating environmentally-relevant exposures to chemicals, supports development of novel biomarkers for chemicals, and advances approaches for interpreting available and new human exposure data.
- Exposure science is essential for evaluating alternative chemicals and identifying chemical products and processes that can reduce negative environmental impacts.



Outcomes for Product Safety

LRI advances research to:

- ▶ Increase consumer confidence in product safety
- ▶ Evaluate the scientific basis for links between chemicals, such as endocrine disruptors, and adverse health outcomes
- Improve understanding of potential risks from new materials, such as nanomaterials



RESEARCH OBJECTIVES

- The LRI program includes projects that extend beyond basic research objectives and have more immediate outcomes and relevance to consumer concerns about product safety and to the effects of chemicals on ecosystems.
- Research includes new approaches to evaluate whether there is a scientific basis for media reports associating everyday exposures to chemicals and human disease.
- The LRI advances understanding of the potential health and environmental risks associated with new materials, such as nanomaterials, as well as the production, use, and disposal of products currently in commerce.

Coordinating a Global Research Portfolio

THE THREE LRI REGIONAL PROGRAMS each support research projects within the priority research areas. These priority areas, which by design are interrelated and interdisciplinary, provide an overall structure for the global LRI program. However, the specific projects funded within these areas can vary from region to region and from year to year depending on industry priorities, financial resources, and other drivers.

A clear advantage of this research diversity among the LRI regions is that it adds both depth and texture to the overall LRI research program. The matrix table describes specific research topic areas within each of the regional programs that highlight this diversity within the three priority areas.



INNOVATING	
CHEMICAL TESTI	NG

UNDERSTANDING EVERYDAY EXPOSURES

TRANSLATING RESEARCH OUTCOMES FOR PRODUCT SAFETY

CEFIC

- Link information at the molecular level to health and environmental impacts
- Support the 3Rs replace, reduce, and refine - for animal testing
- Evaluate effects of cumulative and aggregate exposures in real life scenarios
- Develop predictive models that incorporate environmental stressors
- Apply new populationrelevant concepts for ecosystems
- Reduce complexity and robustly predict health effects <u>using pragmatic approaches</u>

ACC

- Incorporate exposure and dose information to advance interpretation of data from high-throughput assays
- Advance application of cellbased testing systems for chemical safety assessments
- Develop predictive models for estimating consumer exposures
- Improve interpretation of biomonitoring data for environmentally-relevant exposures
- Advance new approaches to evaluate the scientific basis for epidemiological studies linking health effects to chemical exposures
- Develop an innovative framework that integrates multiple data streams and facilitates chemical safety assessment

JCIA

- Develop and evaluate new testing methods, such as those that use stem cells, to improve assessment of chemicals and products
- Innovate high-throughput methods to evaluate large numbers of chemicals
- Develop predictive and practical models for estimating worker exposures
- Research health impacts for groups with potential chemical sensitivities, such as the young and the elderly
- Evaluate the safety of new chemical substances, such as nanomaterials, for future technological developments
- Assess the effects of chemicals on ecosystems and the environment

Communicating Research Results for Decision Making

OUTREACH AND COMMUNICATION are integral elements of the LRI program and are essential for translating the 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. These communication outlets highlight the value of the LRI program and communicate a vision for new policy approaches for chemical management.



Workshops

ANNUAL ICCA-LRI WORKSHOPS showcase the global impact of the research supported by the LRI. Since 2005, these workshops have provided 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. The illustration provides a recent chronology of the ICCA-LRI workshops.

408AMSTERDAM, THE NETHERLANDS

TWENTY-FIRST CENTURY APPROACHES TO TOXICITY TESTING, BIOMONITORING, AND RISK ASSESSMENT

Research, development, and application of the advances in new technologies for toxicity testing and for biomonitoring

CHARLESTON, SC, USA

CONNECTING INNOVATIONS IN BIOLOGICAL, EXPOSURE, AND RISK SCIENCES: BETTER INFORMATION FOR BETTER DECISIONS

Harnessing recent developments in biological technologies to identify hazard and characterize risks from chemical exposures

110 STRESA, ITALY

INTEGRATING NEW ADVANCES IN EXPOSURE SCIENCE AND TOXICITY TESTING: NEXT STEPS

Application of integrated approaches to link exposure science and toxicology for chemical management

111 QUÉBEC CITY, CANADA

ADVANCING EXPOSURE SCIENCE TO IMPROVE CHEMICAL SAFETY

Improving chemical safety assessment through innovations in exposure science

'12 BUDAPEST, HUNGARY

TECHNOLOGIES TO INFORM CHEMICAL SAFETY SCIENCES

Potential applications and implications of new technologies for chemical safety sciences and emerging issues that may influence new developments

113 SANTA FE, NM, USA

WHAT IS NORMAL? IMPLICATIONS FOR CHEMICAL SAFETY ASSESSMENT

Understanding the intersection between chemical exposures and biological function that may initiate early changes but also initiate adaptive responses that result in a return to normal biological function

Global Management

UNDER THE ICCA, Cefic, ACC, and JCIA have forged a coordinated approach that facilitates implementation of the LRI program with common goals and principles. This approach recognizes the independent management by each region as well as the diversity in scientific communities, regulatory requirements, and societal issues among the three geographical regions of Europe, the United States, and Japan.

This global management approach also provides the opportunity to pool the LRI's diverse knowledge on critical industry issues and respond to public and regulatory demands. Through its regional coordination, the global LRI can identify and address future issues of relevance regarding chemical safety assessment.

Governance

STEERING COMMITTEE

The steering committee includes six CEO-level representatives, two each from the Cefic, ACC, and JCIA, who oversee the LRI and report to the ICCA Board of Directors. The steering committee monitors emerging issues related to the global chemical industry and informs the ICCA-LRI Planning Group regarding potential impacts for scientific research.

PLANNING GROUP

The planning group comprises senior company and association managers from the Cefic, ACC, and JCIA regional LRI programs, who provide support to the steering committee as well as feedback to their organizations. The planning group is responsible for program management, efficient delivery of content, and dissemination of research results.









www.icca-chem.org/Home/ICCA-initiatives/Long-range-research-initiative-LRI