

Scientific Contributions to Chemical Policies - Industry Perspective



LRI Global Coordination



- Implemented under the responsibility of three regional centers (US, Japan, and Europe)
 - European Chemical Industry Council (CEFIC)
www.cefic.org/lri
 - American Chemistry Council (ACC)
www.americanchemistry.com
 - Japan Chemical Industry Association (JCIA)
www.nikkakyo.org
- International Council of Chemical Associations (ICCA) provides global coordination

Long-Range Research Initiative (LRI) Objectives



- **Identify and fill gaps in understanding of the hazards posed by chemicals**
- **Improve or develop new methods available for risk assessment**
- **Develop and validate in vitro, modeling and screening methods for assessing e.g. exposure to mixtures and endocrine disruptors**
- **Enable industry, regulators and the public to make informed decisions based on high quality information**

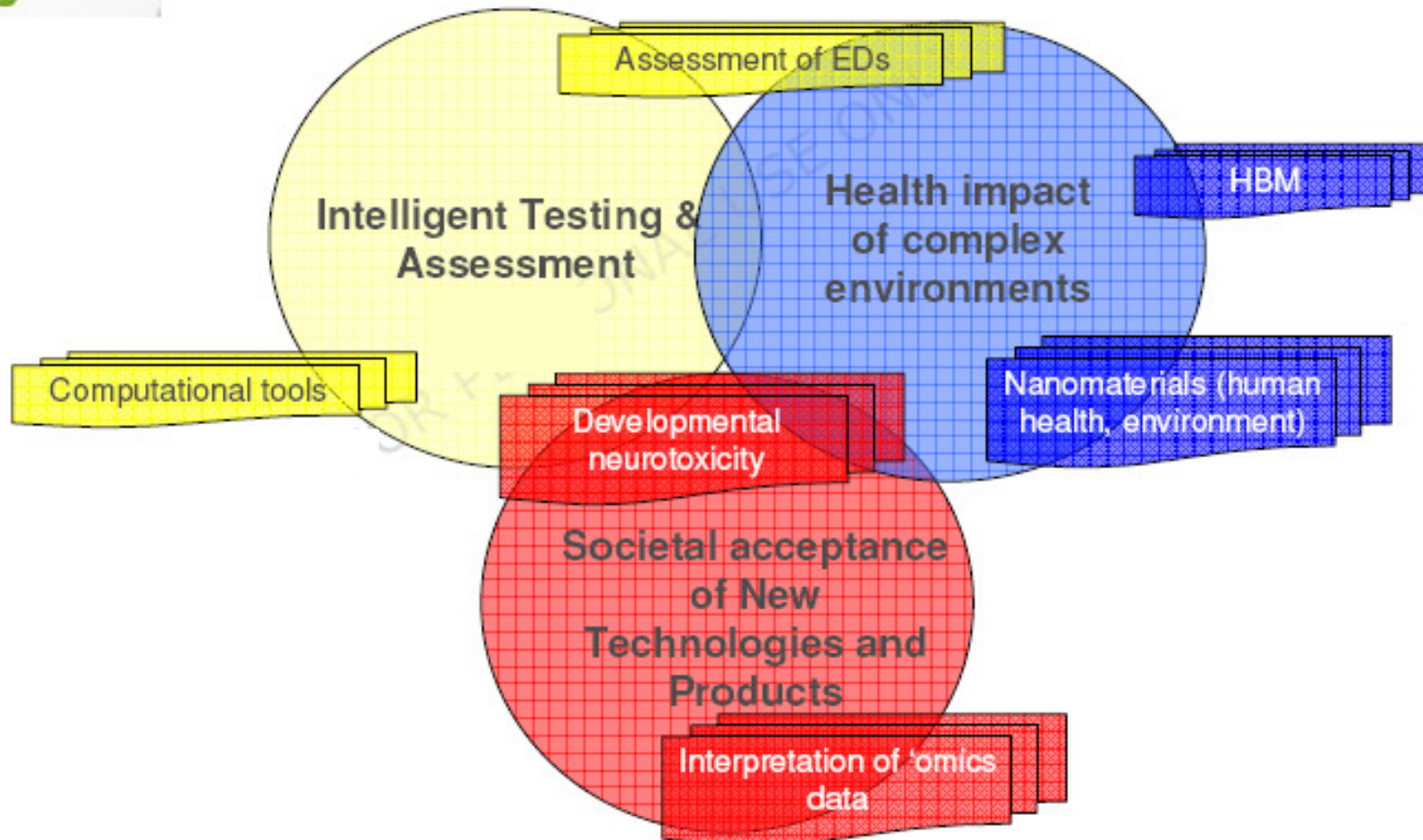
CEFIC LRI Priority Research Areas



LRI
The Long-range
Research initiative



Long-range Research Initiative (LRI) programme

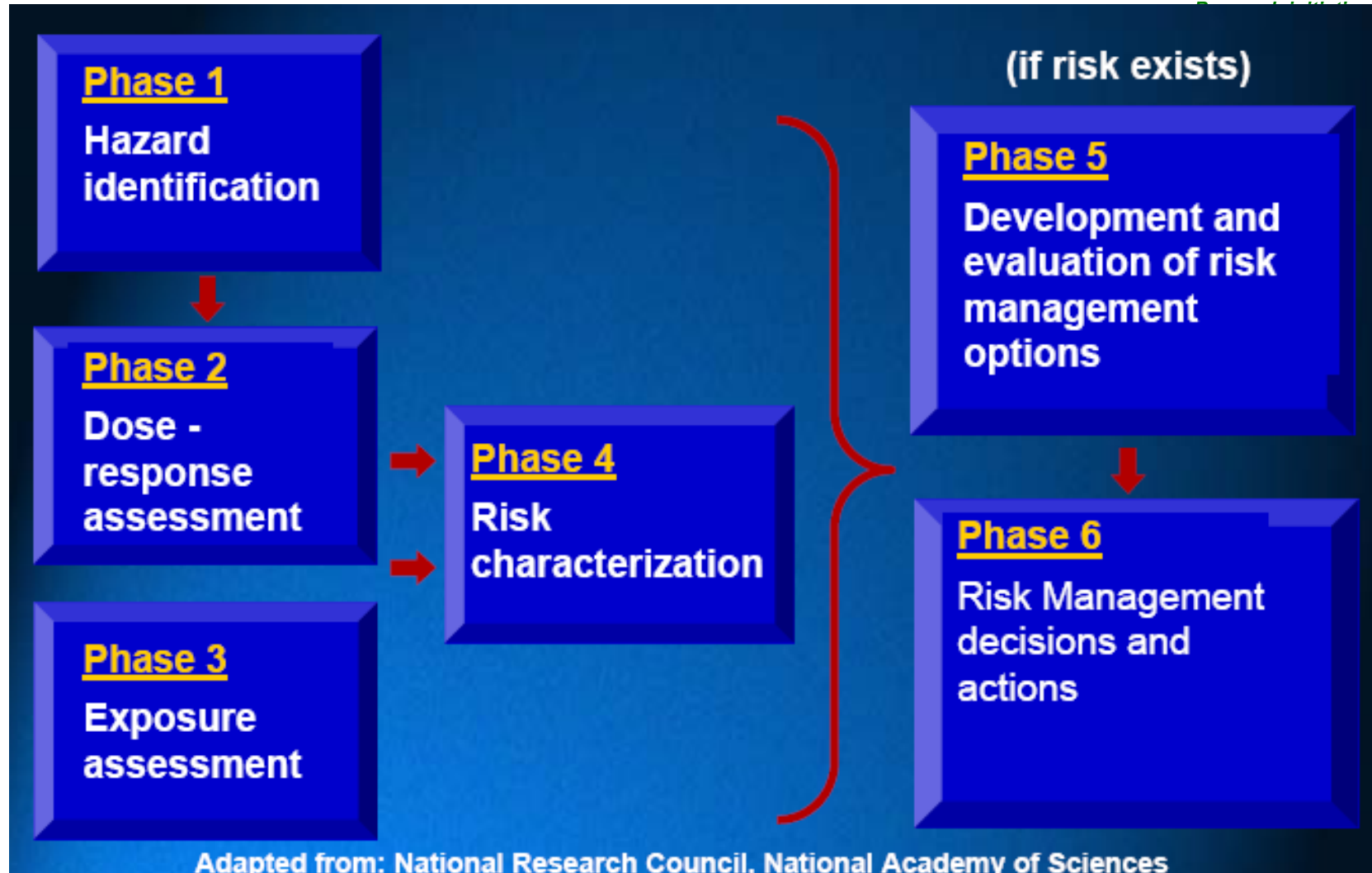


CEFIC LRI Process



- **Research process**
 - Publication of Request for Proposals (RfPs) – open to everyone
 - Requirement to publish peer-reviewed journals
 - External Scientific Advisory Panel (ESAP)
- **Annual €100,000 LRI Innovative Science Award**
 - Since 2004 **for early-career scientists**
 - In cooperation with SETAC and EUROTOX
- **Annual LRI Workshop**
 - Review of progress
 - Development of strategic research areas

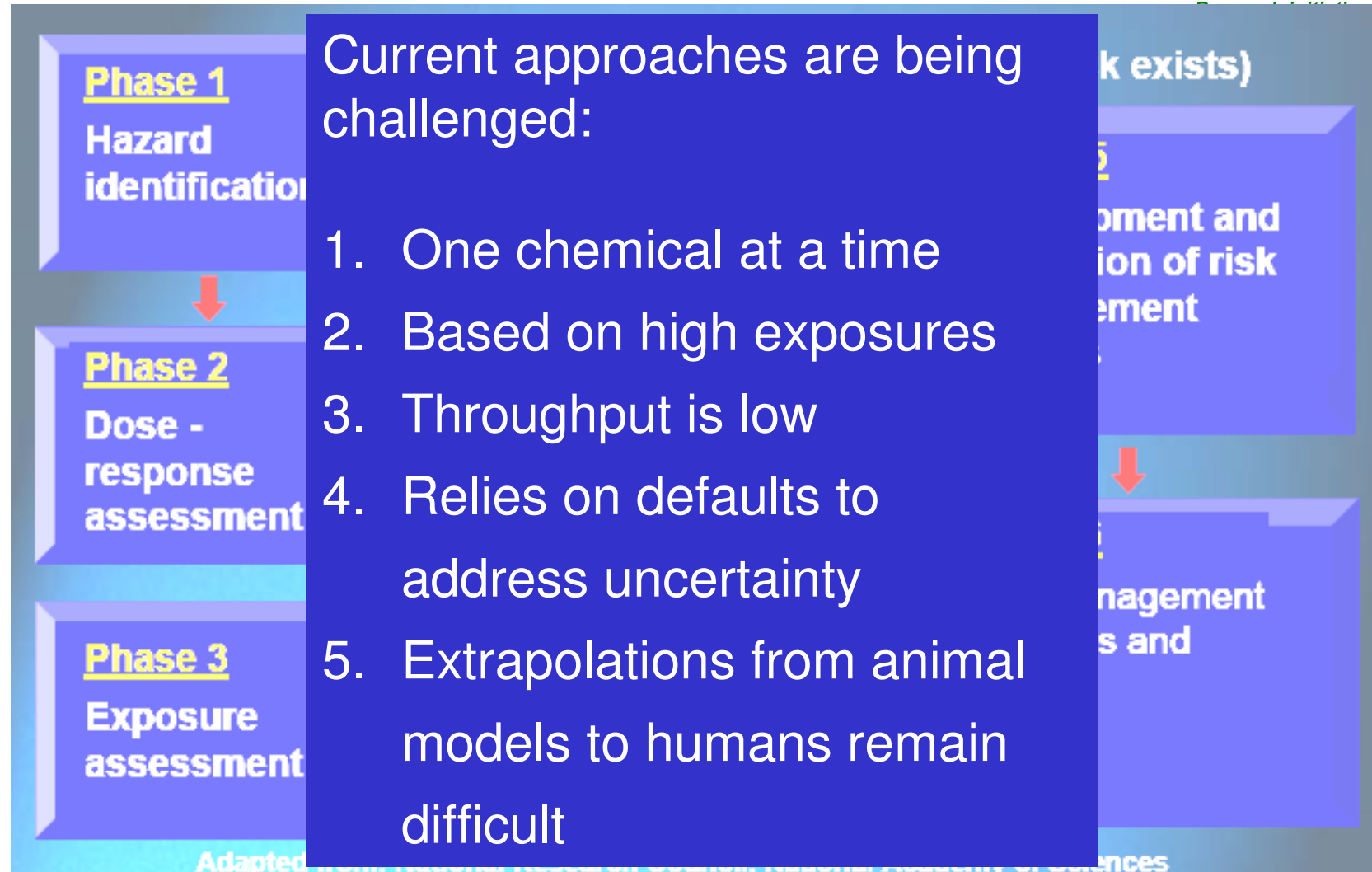
Translating scientific research into regulatory policies



Translating scientific research into regulatory policies



LRI
The Long-range
Institute



CEFIC LRI Areas of priority research



- **Environmental and human exposure assessment (e.g. mixtures)**
- **Risk assessment methodologies**
- **Chemical carcinogenesis**
- **Endocrine disruption**
- **Immunotoxicity and allergy**
- **Respiratory toxicity**
- **Ecosystems dynamics**
- **Neurotoxicity**
- **Atmospheric chemistry**

LRI Projects (Health / ECO)



- **Potential impact on human health**
 - Epidemiological studies
 - Occupational exposure and male fertility
 - Onset of puberty
 - Toxicogenomics
 - Epigenetic effects
- **Endocrine effects in eco-systems**
 - ED in the marine environment
 - Effects on fish in the Elbe River
 - Effects of parasites
 - Fish testing strategy
 - Workshop fish histopathology

LRI Projects (OECD)



- **Sponsorship for OECD Test Guideline (TG) validation through Cefic LRI**
 - Hershberger assay
 - Uterotrophic assay
 - 21-day fish screening assay
 - TG407 28-day rat study
- **Involvement in development of other OECD TGs**
- **Promotion of ITS**
 - European Technology Platform for Sustainable Chemistry (SusChem)

LRI Projects (REACH)



Reprotox testing for REACH higher tonnages

- **New design of mammalian reprotoxicity studies (1- generational vs 2- generational)**
 - Cooperation with EPAA, OECD, ICAPO and governments
 - Development of technical framework (e.g. triggers) by ECETOC Task Force
 - Co-sponsoring of expert workshop
 - Potentially saving 1200 animals per study

LRI Projects (Animal Alternatives)



Computational tools and databases

- OECD (Q)SAR Application Toolbox
- AMBIT tool, support for ToxTree, ToxMatch (ECB)
- RepDose database
- PBPK database and model equation generator

Development of in vitro methods

- Cell systems for DNT
- Cell lines for acute and chronic toxicity
- Use of toxicogenomics

LRI International Cooperation



- **A project in cooperation with OECD, US EPA, and the EU Commission to reduce numbers of animals used in chemical testing**
- **Projects in cooperation with the US National Institutes of Child Health and Human Development to characterize exposures to children more accurately.**
- **In Japan, LRI contributed in several fields to develop new test methods and systems for chemical safety, some of which were promoted to national projects.**

Long-Range Research Initiative (LRI) Benefits



- **High scientific quality of LRI support mutual acceptance of tests, a major breakthrough in minimizing animal testing.**
- **Enables positive engagement with stakeholders (Regulators, Academia, IGO, NGO, Public)**
- **Strengthens the basis for regional and international policies for chemicals**
- **Expert Network, Capacity Building for industry**
- **Since its launch in 1999, LRI has invested over \$200 million USD globally.**

ICCA Initiatives – Contribution to SAICM



Strategic Approach to International Chemicals Management (SAICM)

Responsible Care Global Charter

5. Enhance the management of chemical products worldwide
(Product Stewardship)

Global Product Strategy (GPS)

1. Develop global stewardship guidelines
2. Develop a system for implementation
3. Define risk-based assessment process
4. Partnership with inter-governmental organizations and stakeholders
5. Improve flow of information
6. Share relevant information between industry and with public
7. Communicate GPS (internal / external)
8. Effort to close data gaps and identify emerging issues
9. Develop global advocacy principles



GPS risk assessment of chemicals in commerce



GPS activities on chemicals

- Exceeding a threshold of 1 t/y per company or
- Having a highly toxic / eco-toxic profile generating a major threat to employees or the public even in very small amounts



- Risk characterization performed and risk management measures implemented until the year 2020 (WSSD 2020 goal)



Global Product Strategy (GPS) – Industry's contribution to SAICM



Global Product Strategy (GPS)

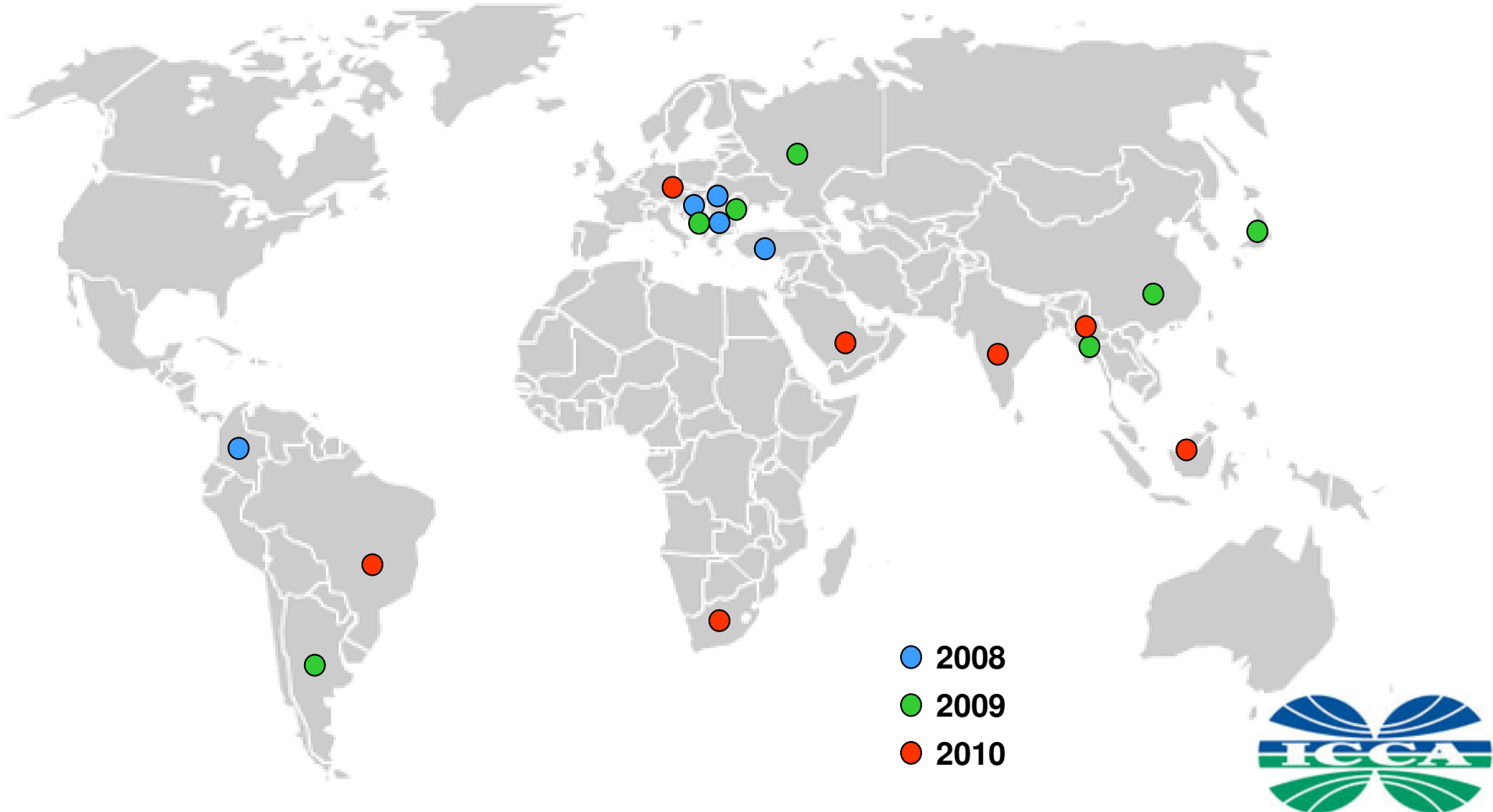
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- ◆ **Regulatory initiatives**
 - EU REACH
 - US TSCA
 - US ChAMP
 - Canadian DSL
 - Japan CSR
 - GHS
 - etc.
 - ◆ **Voluntary initiatives**
 - Responsible Care
 - ICCA HPV
 - Base Set of Information
 - OECD / SIDS
 - **LRI**
 - ◆ **Cooperation**
 - UNEP
 - UNIDO
 - OECD
 - NGOs
 - ICCA internal
 - etc..

Globally consistent approach that accommodates national, historical, cultural and regulatory differences

ICCA Capacity Building – Transition from science to practice



Workshops 2008, 2009 and 2010



ICCA Capacity Building – Transition from science to practice



| Workshops in 2009 | | | |
|--------------------------|--------------------|---------|--------------------|
| | GPS / PS WS | | REACH / GPS |
| 1Q | Thailand | | |
| 2Q | Indonesia | China | |
| 3Q | Argentina | Japan | Bulgaria |
| 4Q | | Croatia | Russia |

| Workshop Plan for 2010 | | | |
|-------------------------------|------------------|----------------|----------------------|
| | GPS/PS WS | PS WS | Tech Training |
| 1Q | India | Thailand | Thailand |
| 2Q | Indonesia | South Africa | |
| 3Q | | Brazil | Brazil |
| 4Q | Saudi Arabia | Central Europe | Central Europe |

We would like your feedback...



- What is the impact of LRI and how can it shape policy developments?
- Where now for LRI? What are the new projects for the years to come ?
- What is the value of the program in the future – from a policy, industry, science or public perspective?
- Do we meet our stakeholder needs ?

Are we asking the right questions?