



LRI in Motion: 2009-2010 projects

Dr Bruno Hubesch

CEFIC, Long-Range Research Programme Manager



cefic

LRI
*The Long-range
Research initiative*

bhu@cefic.be
+32 2 676 7492

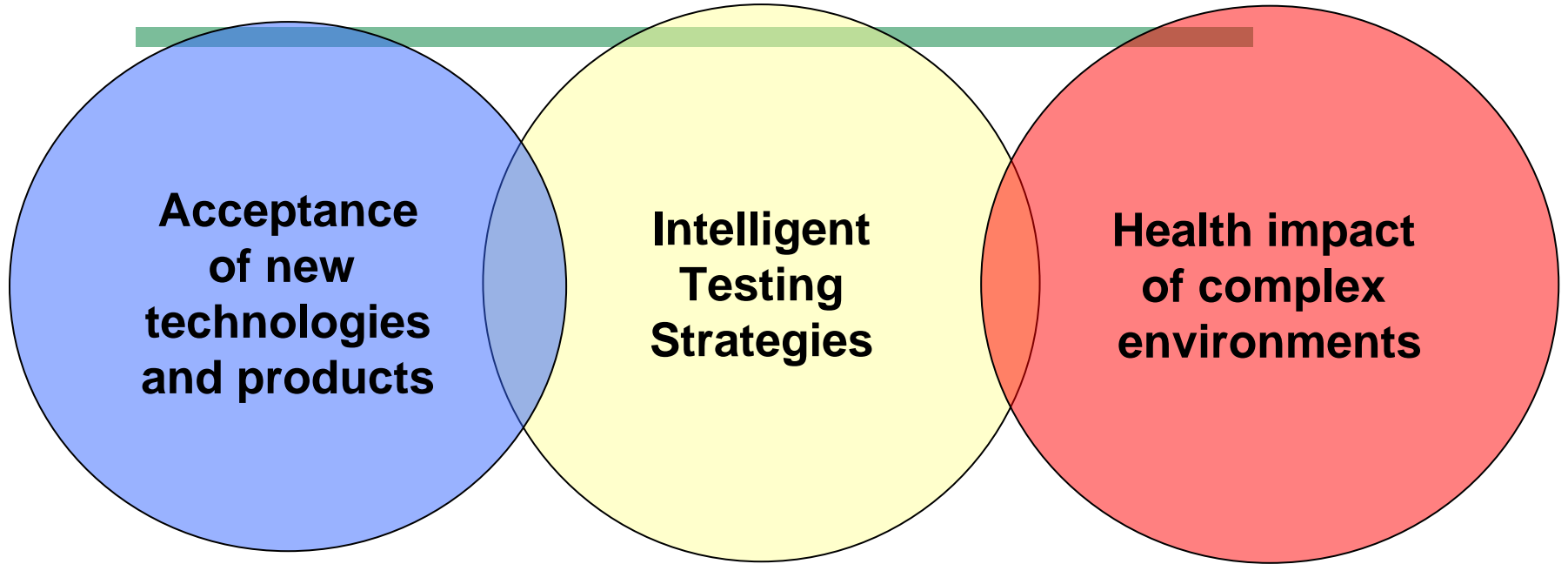


Outline

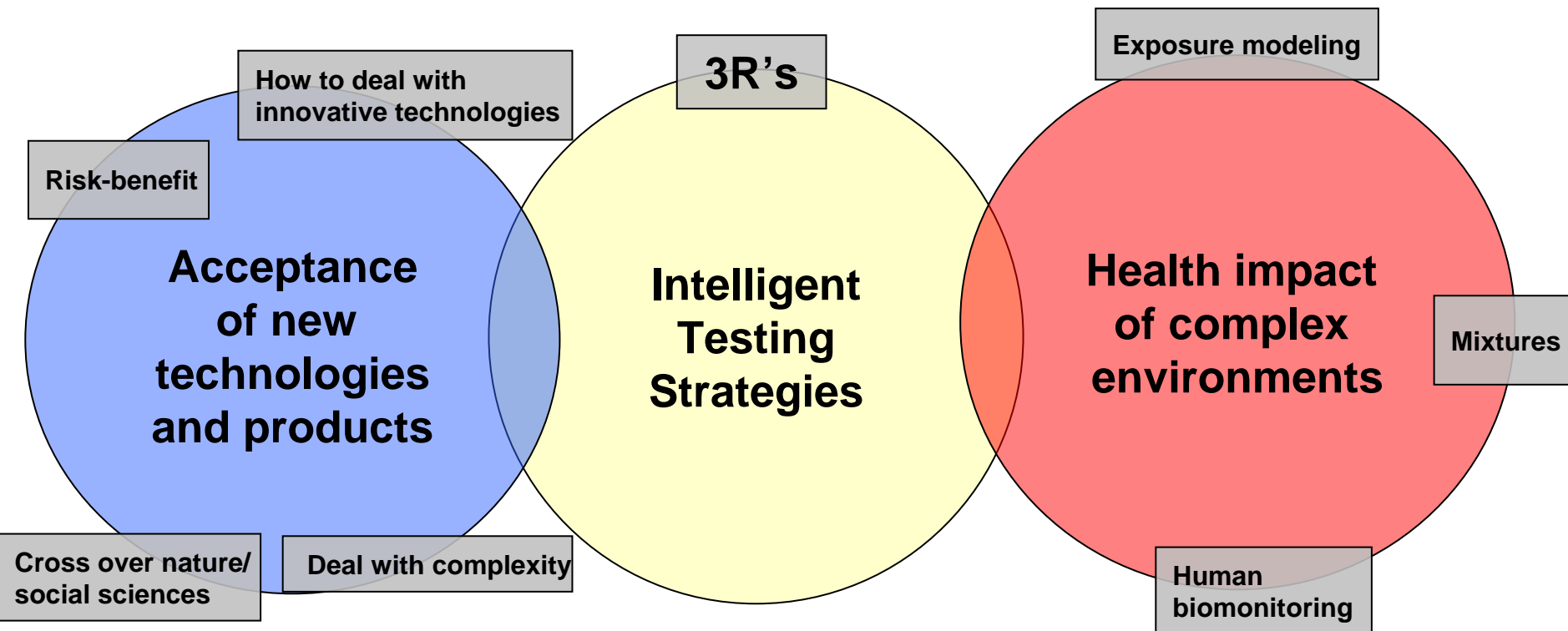
LRI in Motion: 2009-2010 projects

- Fitting the LRI strategy
- Focusing on key chemical policy issues
- 2009-2010 projects
- 2010+ vision

LRI Basics



LRI strategy focus



LRI implementation process



- **Thorough dissemination of RfP's to relevant research groups**
- **High rate of submissions/EoI's – Academia, Gov/Priv Institutes**
- **Selection process via ECETOC Sept-Nov**
- **Selection teams consist of industry and external scientists**
- **Contracting starts end '09 / early '10**

Progress on 2009-2010 LRI Projects



5 critical issues addressed

Exposure

Sensitization

Cancer

Eco Safety

Nanomaterials

Progress on 2009-2010 LRI Projects



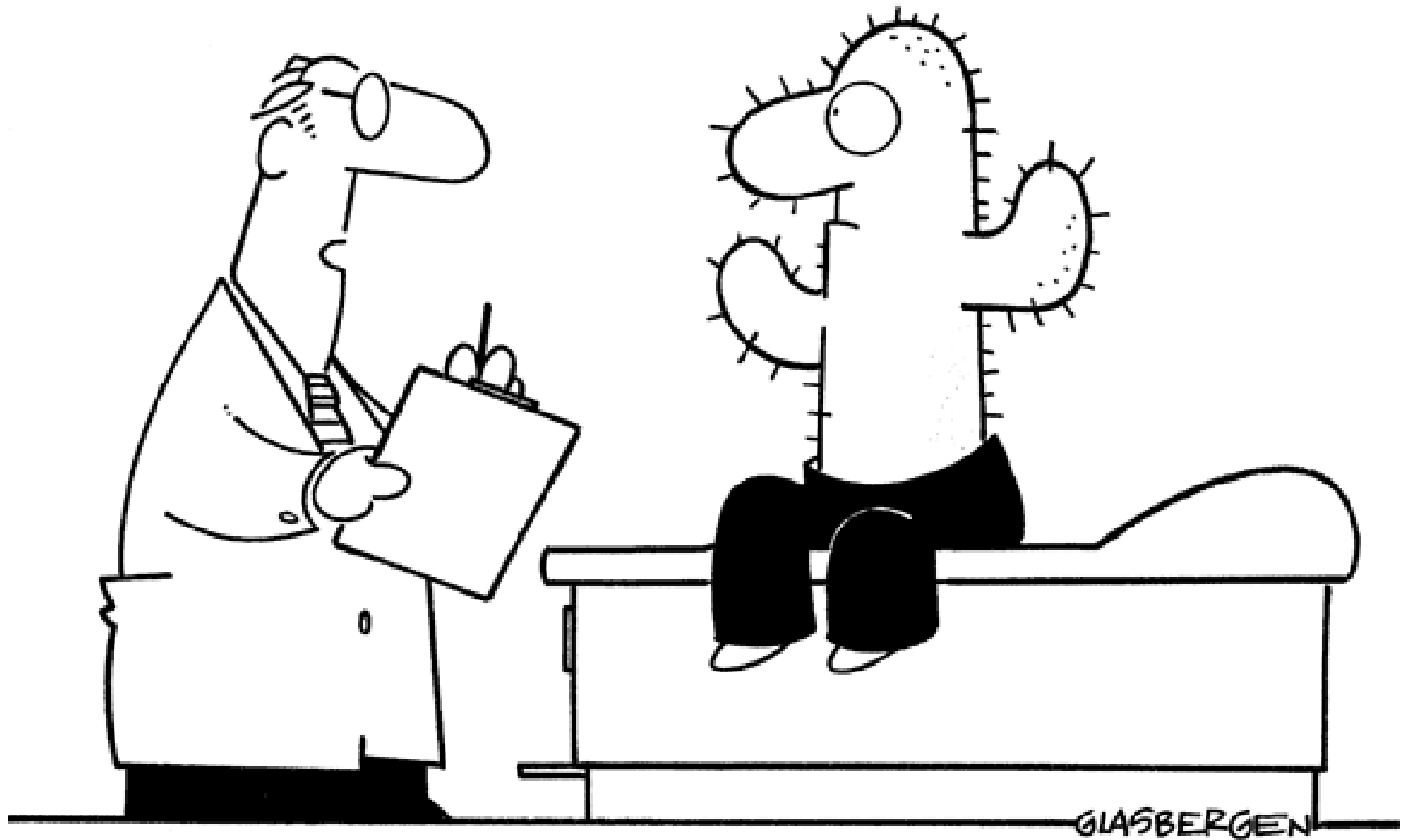
-
- **8 Request for Proposals (RfP's) issued**
 - **5 critical issues addressed**
 1. **Exposure: indoor** environments
 - 1'. **Exposure: realistic estimation to substances mixtures**
 2. Hazard assessment of **sensitizers** via novel markers
 3. Risk factors assessment in breast **cancer**
 4. **Trophic Magnification Factor** estimation in aquatic organisms
 - 4'. **Critical Body Burden** database validation
 - 4''. Abbreviated *in-vivo* **Bio Concentration Factor** test methodology
 5. **Nanomaterials** reproductive toxicity

Exposure



Exposure: Indoor Air





"Let's run some tests before we blame it on indoor air"



Exposure: Indoor Air

B4 – Indoor environments & risk assessments

WHY?

- **EU Parliament request to the EU to come up with a green book on Indoor Air Quality by 2010.**
- **An LRI project is needed to strengthen risk assessment approaches.**

Background

- Historically, ‘simple’ exposure assessment of substances of ‘major concern’ (e.g. carcinogens) or straightforward to characterise (volatile hydrocarbons).
- Today, considerable uncertainties (temporality and co-exposures), exposure varies widely on an inter- and intra-person/place basis.

Objective

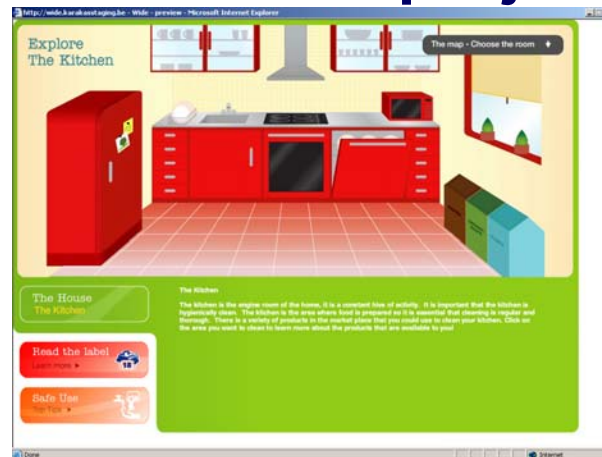
- To develop a methodology that can be reliably applied to predict exposures to defined pollutants (and their inter-relationships).

Indoor Air - Healthy living – solution

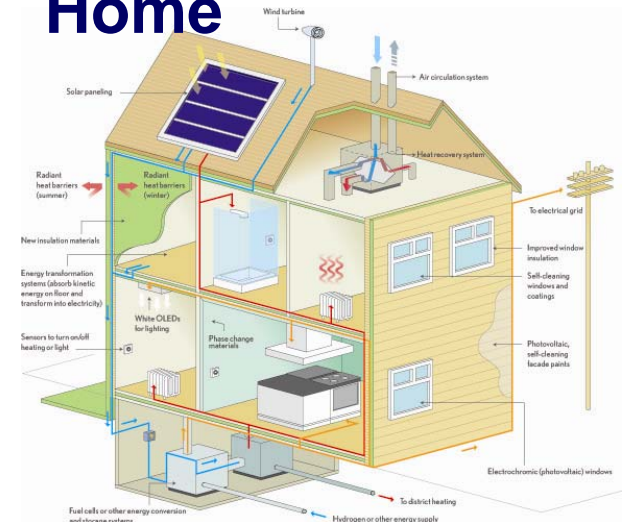


The Long-range
Research initiative

The WIDE project



The Smart Energy Home

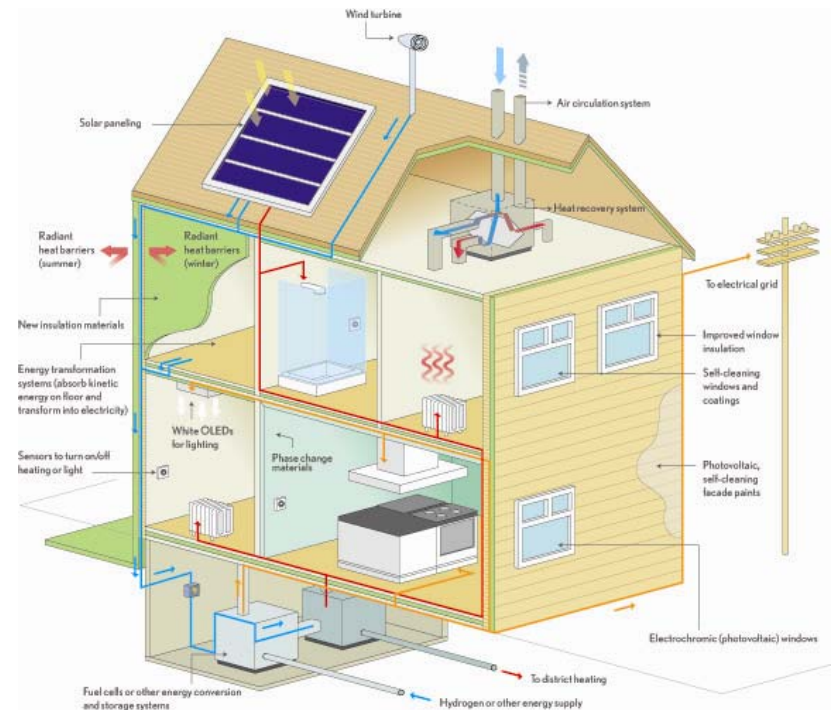




The Smart Energy Home

Combining energy efficiency with increasing comfort and well-being

- Smart materials and surfaces
- Greener home consumables
- Indoor environmental quality systems
- Max. 5-10% additional cost for the final consumer compared to traditional homes



www.smartenergyhome.eu



Exposure: Mixtures

B5 – Realistic estimation of exposure to substances from multiple sources

WHY?

- **Mixtures of chemicals are on agenda at SAICM, WHO (Ministerial Conference, March 2010), European Council Working Party for the Environment**
- **An LRI project is needed to contribute to this upcoming topic (developed with Joint Research Center)**



More background

- Mixture effects can be very complex
- Need to answer open questions using 21st century methodology
- Validated tools need to be developed
- Need contribution on realistic exposure

B5 – Realistic estimation of exposure to substances from multiple sources



Background

- Traditional focus on individual product or article.
- Increasing need to consider multiple sources: ‘Aggregate exposure’.
- Different exposure routes, time scales + frequencies.
- Simple approaches assume unrealistic or impossible conditions.

Objective

- To develop methodologies to estimate aggregate exposure.
- To provide strategies & approaches that allow for quantitative estimations of exposure as realistic as possible.

Cost and Timing



2 years € 400,000

Sensitization



B6 - Improved hazard assessment of chemical sensitizers through testing of novel markers

WHY?

- **Important for REACH implementation in terms of classification labelling (current methodology problematic)**
- **Major area of research within “21st century methods to assessment of risks”**

B6: Improved hazard assessment of chemical sensitizers through testing of novel markers.



Objectives

- Identify and investigate novel markers for the identification of skin sensitizers
- Determine novel markers quantitative correlation with acquisition of skin sensitization and usability for assessment of potency
- Address limitations of the current assays (discrimination between contact allergens and skin irritants and -ideally- for the assessment of complex mixtures
- Determine if novel markers facilitate discrimination between skin sensitizing chemicals and chemical respiratory allergens
- Evaluate novel marker robustness and reproducibility

Cost and Timing

3 years ~€ 700,000

Breast Cancer



CC3 - Assessment of risk factors influencing trends in incidence of breast carcinoma

WHY?

- Increased incidence in Europe and other countries
- Emerging concern: are environmental factors contributing beyond established factors?

CC3 - Assessment of risk factors influencing trends in incidence of breast carcinoma



Background

- **Disease of a multifactor origin: genetic/familial, reproductive/hormonal, lifestyle and environmental**

Objective

- **Summarize literature regarding risk factors for breast cancer, including especially the effect of screening programs**
- **Evaluate the extent in which changes in these risk factors may explain the rise in breast cancer incidence**

Provide recommendations on how potential future research into the association between environmental factors and breast cancer should be conducted

Cost and Timing 9Months €75,000

ECO



Methods & databases

ECO TMF



ECO 15 - Rapid estimation of Trophic Magnification Factors (TMF) using laboratory, field and computer modelling methods in aquatic organisms

WHY?

- **Important for REACH and international policies**
- **Avoid substance to be added to the Persistent Bioaccumulative Toxic (PBT) category, discriminating data rich substances**

ECO 15: Rapid estimation of TMF using laboratory, field and computer modelling methods in aquatic organisms



Background

- TMF values currently calculated from chemical residues
- Alternative methods needed to estimate TMF

Scope

- Search existing techniques for estimating TMF's.
- Develop tools for TMF value estimation, using lab testing, modeling and/or field methods.
- Examine chemicals with field-measured TMFs.
- Evaluate predictive tools with selected chemicals without existing TMF data

Cost and Timing

3 years €500,000

ECO CBB



ECO 16 - Generate a validated Critical Body Burden (CBB) database and validate a CBB chronic toxicity range for narcotics

WHY?

- **Important for REACH for monitoring data interpretation**

ECO 16 - Generate a validated CBB database and validate a CBB chronic toxicity range for narcotics



Background

- Urgent need to improve interpretation of measured environmental exposure data in a toxicological context.
- Use of CBB promising for POPs/PBTs, e.g. for chronic effects
- CBB data available, but not validated and only on acute toxicity
- CBB data can directly be used in risk assessments of PBTs and in interpreting monitoring data
- May also support the feasibility of a 'risk approach' for PBT/POPs

Scope

- Collect + validate available CBB data
- Create database
- Design + execute testing program to validate CBB toxicity range for narcotics

Cost and Timing **3 years** **€500,000**

ECO14bis - Development and validation of an abbreviated in vivo fish bioconcentration factor (BCF) test

Background

OECD TG 305 is costly and uses large numbers of fish.

Scope

- **Develop a shorter, more cost-effective bioconcentration test that uses much fewer fish.**
- **Use training set of chemicals**
- **Consider passive dosing techniques.**

Cost and Timing

2 year \$100,000

ECO14bis - Development and validation of an abbreviated in vivo fish bioconcentration factor test



UNT UNIVERSITY OF NORTH TEXAS™
Discover the power of ideas.

Dr Duane Huggett

**(University of North Texas, Department of Biological Sciences
Institute of Applied Sciences)**

**“Alternative Methodology for Standard Laboratory Fish
Bioconcentration Tests”**

- Link with ongoing OECD statistical evaluation
- Experimental prevalidation over 12-18 months
- Would introduce passive dosing techniques to OECD



Nano Reprotoxicity



N3: Testing and Assessment of reproductive toxicity of Nanomaterials

WHY?

- **Nano is an emerging issue**
- **Data needed for regulatory decision expected by 2012**

N3: Testing and Assessment of reproductive toxicity of Nanomaterials



Background

- So far no study on potential reproductive or developmental toxicity
- OECD WPMN to review the test guidelines

Objective

- Existing OECD reproductive toxicity test guidelines adequate to assess a potential hazard posed by nanomaterials?
- Can the existing guidelines benefit from some revisions to better understand health risks posed by nanomaterials?
- Are there endpoints used to assess the potential hazard of industrial chemicals which may be inappropriate for testing nanomaterials?
- SiO₂ / ZnO via oral administration / inhalation exposure

Cost and Timing

3 year € 800,000

S1 - Societal impact assessment



WAGENINGEN UNIVERSITY
WAGENINGEN UR

Safety Perceptions of new Technologies
(SPOT) – making social and natural
sciences meet

Dr. Amber Ronteltap, Dr. Arnout Fischer,
Dr. Hilde Tobi

Summary / LRI commitment 2009

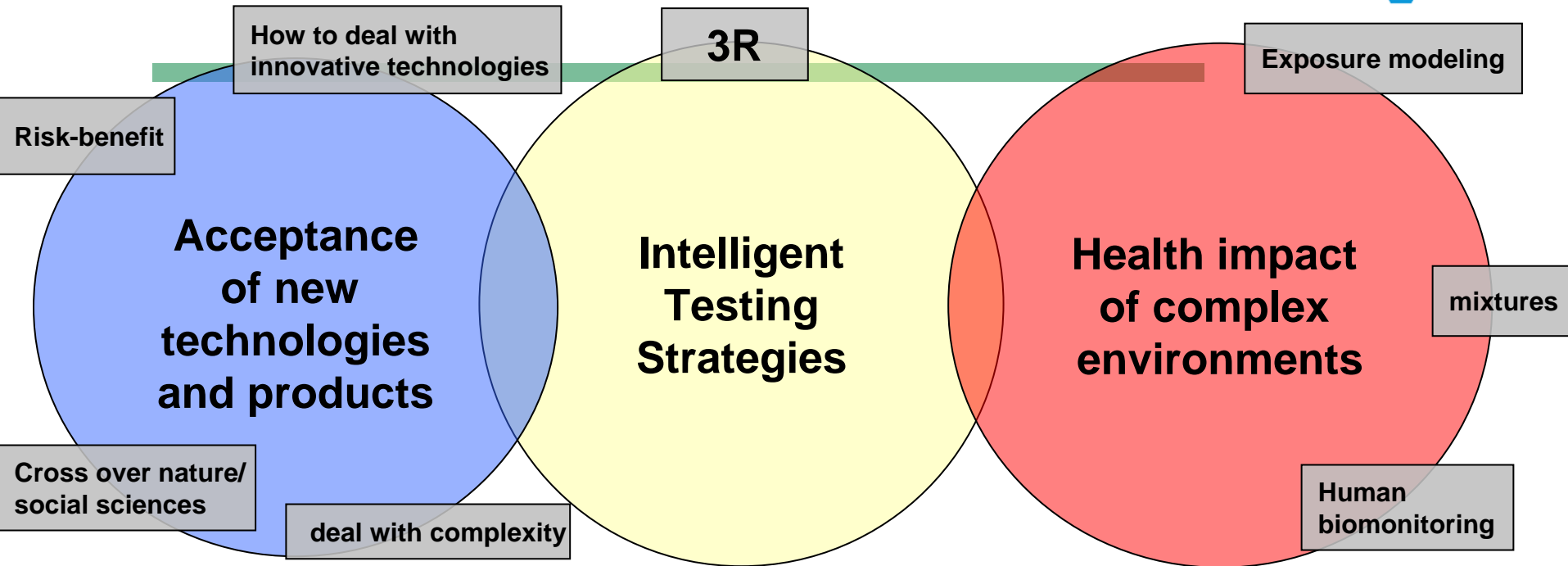


Title of proposal	Project code	Budget
Exposure: indoor environments	B4	€ 400,000
Exposure: realistic estimation to substances mixtures	B5	€ 400,000
Hazard assessment of sensitizers via novel markers	B6	€ 700,000
Risk factors assessment in breast cancer	CC3	€ 75,000
Trophic Magnification Factor estimation in aquatic organisms	ECO15	€ 500,000
Critical Body Burden database validation	ECO16	€ 500,000
Abbreviated <i>in-vivo</i> Bio Concentration Factor test methodology	ECO14bis	€ 70,000
Nanomaterials reproductive toxicity	N3	€ 800,000
	Total	€ 3,450,000

Vision 2010+



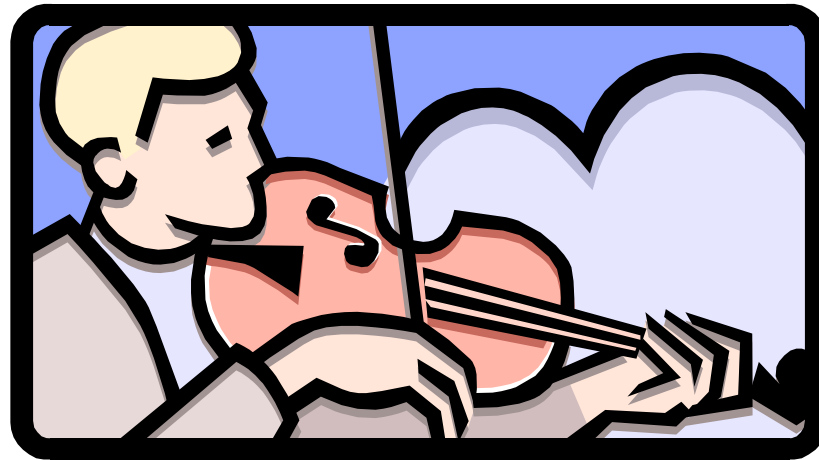
Vision 2010+



- Leverage with EC research
- Link with SusChem / Innovation
- Harvest on + disseminate results



THE END



Thank you !

Dr Bruno Hubesch
bhu@cefic.be
+32 2 676 7492



LRI
*The Long-range
Research initiative*

Back-ups



LRI
*The Long-range
Research initiative*



Five areas of added value of LRI

- **Projects industry regards as important**
- **Early warning on trends through network**
- **Acceptance after industry contributions and proposals**
- **Shaping of science/policy interface by networks**
- **Responsible Care**

LRI project S1



Dr. Amber Ronteltap, Dr. Arnout Fischer, Dr. Hilde Tobi Safety Perceptions Of new Technologies (SPOT) – making social and natural sciences meet.

Background

Societal introduction of new technologies is a place where **social** and **natural sciences** meet
Little is known about determinants of societal acceptance, or natural-social science collaboration
Available knowledge is scattered

Goal of this project

To help steer the introduction of nanotechnology by systematically reviewing lessons from previous technology introductions

Method

Three systematic reviews of scientific papers in English from Web of Science

CEFIC-LRI and biomonitoring..



- 1998: White paper "STOTS - Human Biomonitoring"
- 2001: 1st RfP - Trends & Key developments in human biomonitoring
- 2004: ICCA/EPA/ILSI/CDC/ATDSR workshop on biomonitoring (RTP)
2nd RfP - Background values, inter- & intra-individual variations
- 2005: ICCA workshop on biomonitoring (Paris)
- 2005: ECETOC Task Force on Biomonitoring "Guidance for the Interpretation of Biomonitoring Data" → research issues
- 2006: ICCA workshop on biomonitoring: "Making sense of biomonitoring data" (Minneapolis)
3rd RfP - Interpretation: biomonitoring guidance values
- 2007: ICCA/EPA workshop on biomonitoring: "Public Health Applications" (Research Triangle Park)
- 2008-2008: ICCA/EPA workshops biomonitoring/exposure

5.1 LRI New Projects to be started in 2009 (1/2)



PRIORITY / SUBJECT	WHY IS IT IMPORTANT?	Total Budget	Duration estimate
1A. NANOMATERIALS-REPROTOXICITY	Nano is an emerging issue and data are needed by 2011 in order to impact regulatory decision on nanomaterials expected in 2011/2012.	800k	2-3Y
1B. EXPOSURE: Indoor environments & risk assessment	The EU Parliament has requested the EU to come up with a green book on Indoor Air Quality by 2010. An LRI project is needed to strengthen risk assessment approaches.	400k	2Y
1C. EXPOSURE: Realistic estimation of exposure to substances from multiple sources	Mixtures of chemicals are high on agenda at SAICM and WHO in 2010 (i.e. WHO Ministerial Conference 2010). An LRI project is needed to contribute to this upcoming topic to be started latest in January 2010.	400k	3Y

5.2 LRI New Projects to be started in 2009 (2/2)



PRIORITY / SUBJECT	WHY IS IT IMPORTANT?	Total Budget	Duration estimate
1D. ENVIRONMENTAL: Rapid estimation of Trophic Magnification Factor using laboratory, field, and computer modeling methods	Important for REACH and international policies to avoid substance to be added to the Persistent Bioaccumulative Toxic (PBT) category, discriminating data rich substances.	500k	2Y
2. ENVIRONMENTAL: Generate a valid CBB database and validate a CBB chronic toxicity range for narcotics	Important for REACH for monitoring data interpretation	500k	3Y
3A. OMICS: Improved hazard assessment of chemical sensitizers through testing of novel markers	Omics are as a major areas of research on the LRI Agenda “21st century methods to assessment of risks”. This long term research can also start early 2010.	700k	2-3Y
3B. ENVIRONMENTAL: Abbreviated bioconcentration test	Faster/cheaper methodology in timeline of new EU chemicals regulations.	70k	1Y
		3.4 M	