Risk Governance for Key Enabling Technologies

Society for Risk Analysis
Policy Forum

Conference Program

Cultural Center Don Orione Artigianelli
Venice, Italy • 1-3 March 2017

Organizers

SRA Worldwide Headquarters

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Scientific Committee

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Antonio Marcomini, University Ca' Foscari Venice (IT, Co-Chair)
Danail Hristozov, University Ca' Foscari Venice (IT, Co-Chair)
Keld Alstrup Jensen, National Research Centre for the Working Environment (DK)
Myriam Merad French National Center for Scientific Research (FR)
Patrick Boisseau, CEA (FR)
Marie Valentine Florine, International Risk Governance Council (CH)
Dan Vallero, Environmental Protection Agency (USA)
Tim Malloy, University of California, Los Angeles (USA)
Christopher Cummings, Nanyang Technological University (SG)
Vicki Stone, HWU (Scotland)

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Society For Risk Analysis Policy Forum
2017 Conference Program • 1-3 March 2017

Risk Governance for Key Enabling Technologies

The continued development and growing opportunities for commercialization of key enabling technologies (e.g., nanotechnology, synthetic biology, biomaterials) raises fundamental environmental health and safety (EHS) challenges for regulators in various governments. Even though existing practices for risk assessment and management (RA&M) are applicable to these technologies, their implementation requires information that is difficult to obtain given the limited availability of quantitative data to populate models corresponding to material exposure, hazard, and consequences. To facilitate regulatory decision making for emerging technology research and innovation and account for corresponding EHS risks, a comprehensive risk governance (RG) framework must account for both qualitative and quantitative data under high uncertainty and local/regional requirements for technology governance.

About the SRA Forum

The SRA Forum will provide discussion of current initiatives that are centered on refining the risk governance of emerging technologies through the integration of traditional risk analytic tools alongside considerations of social and economic concerns. Such an approach will help account for objective and subjective information alike in order to foster effective governance for emerging technologies with uncertain and potentially consequential risks. The Forum will develop summaries of current activities of multiple efforts in the United States, European Union, Asia, Latin America, and elsewhere, and will indicate opportunities for future meetings and research.

Join us in Venice, Italy

The SRA Forum will be held on 1–3 March 2017 at Cultural Center Don Orione Artigianelli, located in the historic center of Venice, Italy. The Cultural Centre is a vast architectural complex composed by four cloisters and other numerous buildings dating back from 15th century. Originally established as a monastery, today the center features modern, fully-equipped conference and accommodation facility, located in the city centre of Venice, behind Gallerie dell'Accademia with direct overview on the Zattere quayside and Giudecca Canal.

Target Audience

The SRA Forum is targeted for personnel from research and academic institutions as well as from industry, governmental agencies, and other relevant organizations. The forum is aimed at senior researchers interested in nanotechnology, industrial and medical biotechnology, synthetic biology, advanced materials, and advanced manufacturing technologies. The convergence of various perspectives on these topics will create helpful discussion related to the risk perception, management, and governance of these emerging technologies.

Topics of Discussion

The discussion topics for this Forum will center on emerging risk issues of key enabling technologies. These include issues of traditional risk assessment (detection, toxicology, fate, and material exposure), risk communication (stakeholder engagement), and more novel approaches (risk governance under uncertainty). In this vein, discussion will focus on both the measurement and assessment of emerging technology risk on one hand, and the characterization and governance of such technologies on the other.

Call for Late Breaking Posters

Present your findings on a global stage! Presenters will have the opportunity to present in front of a large international audience. Submit your abstract at birenheide.com/sra/rpforum/abstracts.php

Call for Journal Papers

The Editors-in-Chief and Editorial Board of the Springer journal Environment, Systems, & Decisions announce a Call for Papers for a special Issue of the journal to focus on emerging technology risk management and governance. Submissions due June 15, 2017. Contact Dr. Benjamin Trump (bdt2011@gmail.com) with inquiries.

Call for Book Chapters

Drs. Trump, Cummings, Kuzma and Linkov, are inviting your contribution to the book on "Risk Governance for Synthetic Biology" that will be published by Springer in 2018. Contact Dr. Benjamin Trump (bdt2011@gmail.com) with inquiries or please talk to Dr. Linkov, Cummings or Trump during the meeting.

Workshop

SUN-CaLIBRAte Stakeholders Workshop

From Nano Risk Management to Innovation Governance: Developing State of the Art, Reliable and Trustable Risk Governance Tools for Nanomaterials

2nd - 3rd March 2017

The event aims to engage stakeholders to:

- Discuss stakeholders' needs, priorities and views on managing risks in the innovation, launch, and post marketing monitoring process
- Present state of the art achievements on nano-risk governance, basing on the aims of the caLIBRAte and outcomes of the concluding SUN project
- Explore the SUN decision support system for risk –benefit evaluation and management
- Contribute to define the criteria and function of the future caLIBRAte Systems of Systems risk governance framework

The workshop will be held within the SRA Policy Forum: Risk Governance for Key Enabling Technologies. For more information click here.

Hotel Accomodations

Accommodation at special rates has been blocked by the conference organizers in recommended hotels near the conference venue. Special conference rates are available for bookings in a variety of hotels within different deadlines. Rates are in Euros, per room/night and include 10% VAT and buffet breakfast. City tax is not included and its amount may vary according to the hotel category, from about 2 to 5 Euros per day.

CENTRO CULTURALE DON ORIONE ARTIGIANELLI – Conference Venue
Zattere Dorsoduro 909/A
30123 Venice, Italy
0039 041 522 40 77

HOTEL PAPADOPOLI
S. Croce, 245
30135 Venice, Italy
0039 041 71 04 00

HOTEL SATURNIA
Calle Larga XXII Marzo, 2398,
30124 Venice, Italy
0039 041 520 83 77

HOTEL MONACO & GRAND CANAL
Piazza San Marco, 1332
30124 Venice, Italy
0039 041 520 02 11

PALAZZO SELVADEGO
Piazza San Marco, 1332
30124 Venice, Italy
0039 041 520 02 11

HOTEL LA FENICE ET DES ARTISTES
San Marco, 1936
30124 Venice, Italy
0039 041 523 23 33

HOTEL PAUSANIA
Dorsoduro, 2824
30123 Venice, Italy
0039 041 522 20 83

HOTEL TIVOLI
Dorsoduro 3838,
30123 Venice, Italy
0039 041 524 24 60

Please contact Congress Studio Venezia International s.a.s. at info@congressvenezia.it should you have any questions.

Keynote Speaker

Lieutenant General Thomas P. Bostick, PhD (Intrexon Corporation; 53d Chief of Engineers (Retired) US Army)

Gala Dinner (included in registration)

Thursday, March 2, 2017: 19:30
Restaurant Poste Vecie, San Polo, 1608, 30124 Venezia
www.postevecie.com

Map

Places

- Centro Culturale Don Orione Artigianelli
- Poste Vecie
- Hotel Papadopoli Venezia MGallery by Sofitel
- Hotel Saturnia & International
- Hotel Monaco & Grand Canal
- HOTEL PALAZZO SELVADEGO
- Hotel La Fenice et Des Artistes
- Hotel Pausania
- Don Orione Artigianello
- Albergo Tivoli
- Zattere stop
- Accademia stop
- Tronchetto stop

Car Park

- Venezia Tronchetto Parking
- Garage San Marco Venezia
- Autorimessa Comunale
- Parcheggio Sant'Andrea

How to get there

From Accademia stop to Don Orione Artigianelli

A Accademia stop

B Centro Culturale Don Orione Artigianelli

From Zattere stop to Don Orione Artigianelli

A Fondamenta Zattere Ai Gesuati, 917a, 30123 Venezia, Italia

B Centro Culturale Don Orione Artigianelli

From Tronchetto parking to Tronchetto stop

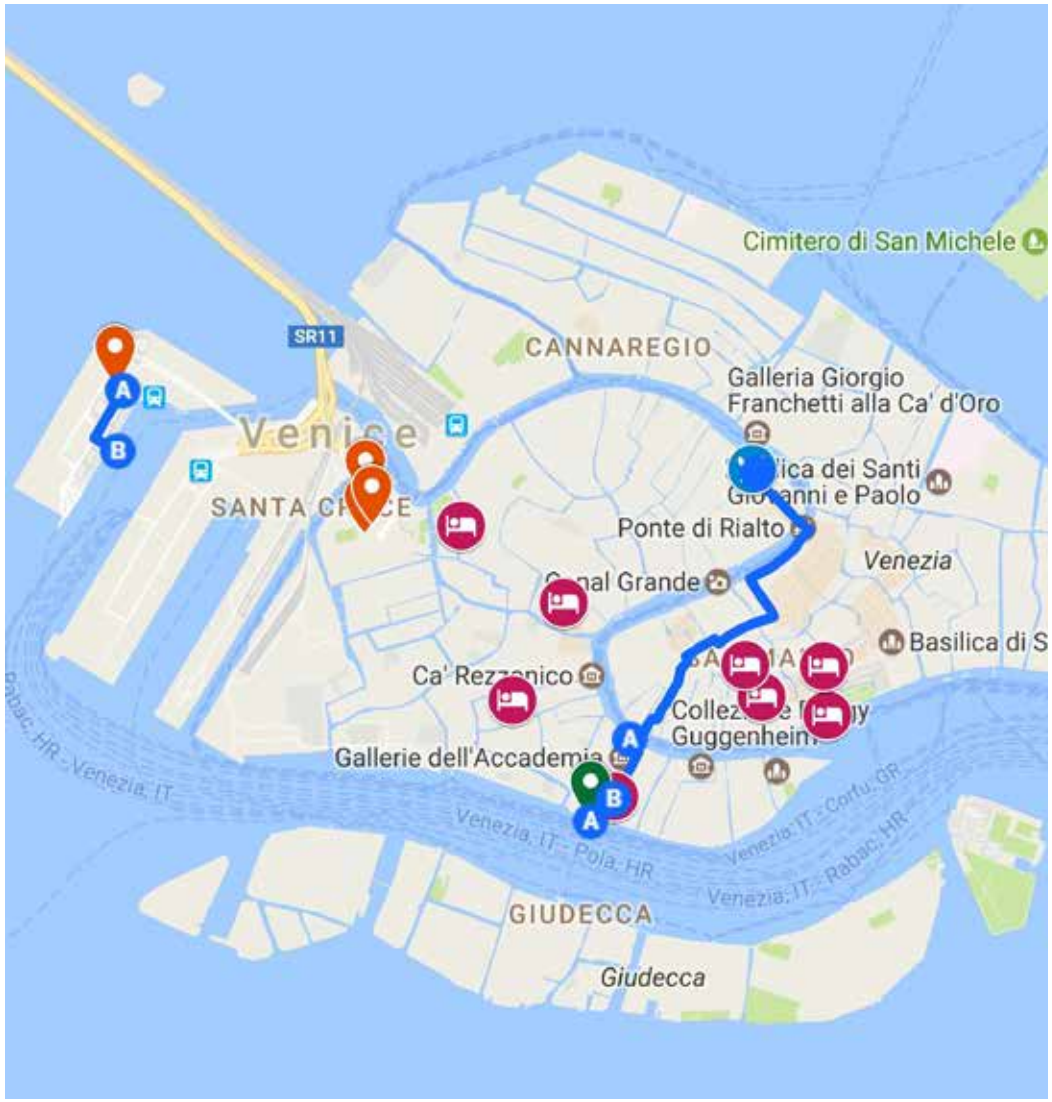
A Isola Nova del Tronchetto, 500, 30135 Venezia, Italia

B Tronchetto stop

From Don Orione to Poste Vecie Restaurant

Centro Culturale Don Orione Artigianelli

Poste Vecie, San Polo, Venezia, VE



Final Agenda

Wednesday, March 1, 2017

15:00 – 16:00 **Registration**

16:00 – 17:00 **Opening Addresses**
University Ca Foscari - Antonio Marcomini, EC - Georgios Katalagarianakis, JRC - Elke Anklam, SRA – Jim Lambert
Aula Magna

17:00 – 18:00 **Introduction to the Conference Goals and Objectives**
Danail Hristozov, Igor Linkov
Aula Magna

18:00 -18:30 **Discussion**
Moderators: Danail Hristozov, Igor Linkov
Aula Magna

18:30 **Welcome Reception**

Thursday, March 2, 2017

08:00 – 08:15 **Registration**

08:15 - 09:45 **Panel 1: Challenges of Emerging Threats: Framing, Needs and Policy**
Panelists: Anklam, Vermeire, Alstrup Jensen, Dana
Moderator: Tim Malloy
Aula Magna

09:45 - 10:30 **Debate: Is the Traditional RA Applicable to KETs or Should the Paradigm be Changed?**
For Traditional RA - Bernie Goldstein
For Paradigm Change - Igor Linkov
Moderator: Ben Trump
Aula Magna

10:30 - 11:00 **Coffee Break**
Sala Vivaldi

11:00 - 12:30 **Panel 2: Risk Governance of KETs– Where does the Field Go?**
Panelists: Seager, Stone, Nowack, Marcomini
Moderator: Marie-Valentine Florin
Aula Magna

12:30 – 13:30 **Lunch**
Sala Vivaldi

13:30 - 14:45 **Parallel Session 1**

- Risk Governance and Policy for Emerging Technologies
  Benighaus, Rickerby, Goodsite, Berube
  Sala Goldoni
- Risk Assessment of Manufactured Nanomaterials
  Mattsson, Schlich, Wigger, Pang, Prina-Mello
  Sala Canova
- Synthetic Biology Applications and State of Science
  Lull, Trump, Landrum, Foss Hansen
  Aula Magna

14:45 - 16:00 **Parallel Session 2**

- Nanotechnology Risk Governance
  Poerschke de Quevedo, Mullins and Malsch, Ahmad, Zabeo
  Sala Goldoni
- Predictive Risk Assessment of Nanomaterials
  Oosterwijk, Norppa, Costa, Lewandowski, Lippy
  Sala Canova
- Synthetic Biology for Zika Virus and Other Applications
  Cummings, Lane and Sperry, Hallsby
  Aula Magna

16:00 - 16:30 **Coffee Break**
Sala Vivaldi

Final Agenda

16:30 - 17:45 **Parallel Session 3**

- Sustainability and Lifecycle of Nano-enabled Products
  Semenzin, Olaru, Steinfeldt, Chappell
  Sala Goldoni
- Governance for Synthetic Biology and Advanced Materials
  Pereira, Dikmen Toker, Hayes, Malloy
  Sala Canova
- Late Breaking Session 1: Risk Governance of KETs
  Goldstein, Walhout, Palma, Florin
  Aula Magna

17:45 - 19:00 **Poster Session**
2nd Floor

19:30 **Gala Dinner**
Antica Trattoria Poste Vecie

Friday, March 3, 2017

08:00 – 08:15 **Registration**

08:15 - 09:30 **Parallel Session 4**

- Case Studies in Governance and Management
  Tonelli, Khan, Virine, Ferson
  Sala Goldoni
- Risk Management and Safer Design of Nanotechnology Products
  Oksel, Pingue, Subramanian, Wang
  Sala Canova
- Late Breaking Session 2: Synthetic Biology:
  Risks and Opportunities
  Liss, Vermeire, Perkins, Seager
  Aula Magna

09:30 - 10:15 **Keynote Presentation: Challenges of Risk Governance in Government and Industry**
General (Ret) Thomas Bostick, PhD,
with introduction from Jim Lambert
Aula Magna

10:15- 10:45 **Coffee Break**
Sala Vivaldi

10:45 - 12:00 **Parallel Session 5**

- Regulatory Science and Risk Management
  Soares Alberto, Le Gal, Aoyagi, Renn
  Sala Goldoni
- Case Studies in Medical Technologies and Emerging Materials
  Ionescu, Mennen, Browayes, Boisseau
  Sala Canova
- Late Breaking Session 3: Risk Governance of Nanotechnologies
  Schoonjans, Davis, Prodanov, Shin, Macian
  Aula Magna

12:00 – 13:00 **Lunch**

13:00 - 14:15 **Panel: KETs: Striking the Balance between Regulation and Innovation**
Panelists: Prina-Mello, DellaSala, Perkins, van Teunenbroek, Boisseau
Moderator: Dan Vallero
Aula Magna

14:15 - 15:30 **Panel: Communication and Stakeholder Engagement Challenges**
Panelists: Renn, Palma, Berube, Cummings, Malsh
Moderator: Myriam Merad
Aula Magna

15:30 - 16:30 **Coffee Break and Poster Session**
Sala Vivaldi + 2nd Floor

16:30 - 17:30 **Concluding Discussion**
Moderator: Igor Linkov and Danail Hristozov
Aula Magna

17:30 - 17:45 **Farewell and Closing Remarks**
Antonio Marcomini
Aula Magna

Technical Program

Presenter's name is asterisked (*) if other than first author.

Parallel Session 1

13:30 – 14:45

1-A

Risk Governance and Policy for Emerging Technologies

Chair: Alexander Jovanovic

Sala Goldoni

13:30 **1-A.1**

Prevention-Based Governance for Synthetic Biology: A Thought Experiment

Malloy TF

UCLA School of Law

13:45 **1-A.2**

Risk Governance of emerging risks: An application of analytic-deliberative policy making

Benighaus L

Dialogik gGmbH

14:00 **1-A.3**

Approaches to Risk Assessment for Nanomaterials in European Industry

Rickerby DG

European Commission, Directorate General Joint Research Centre

14:15 **1-A.4**

Reframing Zika

Berube D, Hallsby GA, Hammond R, Adams M, Will R

North Carolina State University

13:30 – 14:45

1-B

Risk Assessment of Manufactured Nanomaterials

Chair: Danail Hristozov

Sala Canova

13:30 **1-B.1**

Imminent challenges for risk assessment of manufactured nanomaterials

Mattsson MO, Simkó M

SciProof International AB, Vaktpoststigen 4, 83132 Östersund, Sweden

13:45 **1-B.2**

Tool for the hazard assessment of nanomaterials focusing on realistic environmental conditions

Schlich K, Hund-Rinke K

Fraunhofer Institute for Molecular Biology and Applied Ecology

14:00 **1-B.3**

Next steps in environmental risk assessment of engineered nanomaterials considering material-specific properties

Wigger H, Nowack B

EMPA - Swiss Federal Laboratories for Materials Science and Technology

14:15 **1-B.4**

Probabilistic approach for assessing risk to infants from nano-enabled products

Pang CB, Hristozov D, Zabeo A, Pizzol L, Tsang MP, Sayre P, Marcomini A

Ca

14:30 **1-B.5**

Prina-Mello

13:30 – 14:45

1-C

Synthetic Biology Applications and State of Science

Chair: Steffen Foss Hansen

Aula Magna

13:30 **1-C.1**

The role of perceived risk of genetic engineering (GE) on public support for the release of GE mosquitoes to reduce the spread of Zika virus

Lull RB, Brossard D, Hallman WK, Jamieson KH

University of Pennsylvania, University of Wisconsin-Madison, Rutgers University

13:45 **1-C.2**

A Comparative Analysis of Variations in Synthetic Biology Regulation

Trump BD

US Army Corps of Engineers

14:00 **1-C.3**

Disclosure of Open and Transparent Research Practices and Public Trust

Landrum AR, Hilgard J, Lull RB, Akin H, Jamieson KH

University of Pennsylvania

14:15 **1-C.4**

Categorization of Advanced Materials and European Environmental Regulation

Hansen SF, Pelsy F, Broomfield M, Kobe A

Technical University of Denmark; Milieu Consulting; Ricardo Energy & Environment; European Commission DG Environment

Technical Program

Presenter's name is asterisked (*) if other than first author.

Parallel Session 2

14:45 - 16:00

2-A

Nanotechnology Risk Governance

Chair: Myriam Merad

Sala Goldoni

14:45 **2-A.1**

The late incorporation of risk governance into nanotechnology policy in Brazil

Quevedo JP, Invernizzi N

Universidade Federal do Paraná

15:00 **2-A.2**

Pitfalls of interdisciplinarity: finding common ground between nanorisk governance and nanoethics

Malsch I

Malsch TechnoValuation

15:15 **2-A.3**

Reflections on EU projects SANOWORK and SUN; A Risk Management Perspective

Mullins M, Murphy F

University of Limerick

15:30 **2-A.4**

Developing Risk Radar for emerging risks in the area of nano-technology/engineered nanomaterials for the EU Project caLIBRAte

Jovanovic A, Ahmad M, Quintero FA, Markovic N

Steinbeis Advanced Risk Technologies GmbH

15:45 **2-A.5**

SUNDS, a decision support system for nanotechnology risk assessment & management based on multi attribute value theory

Zabeo A, Hristozov D, Semenzin E, Pizzol L, Subramanian V, Basei G, Marcomini A

Ca'Foscari University Venice

14:45 - 16:00

2-B

Predictive Risk Assessment of Nanomaterials

Chair: Lang Tran

Sala Canova

14:45 **2-B.1**

Review of Human Risk Assessment Models Considering Their Input Requirements and Applicability During Product Innovation Stage-Gates. First Results From Eu H2020 'Calibrate' Project

Oosterwijk T, Franken R, Fransman W, Dalmaso M, Poikkimaki M, Säämämem A, Stockmann-Juvala H, Kanerva T, Astrup Jensen K, Stierum R

TNO; Tampere University of Technology; Finnish Institute of Occupational Health; NCRWE

15:00 **2-B.2**

Genotoxic hazard assessment of 31 nanomaterials in human bronchial epithelial cells

*Vales G, Catalán J, Correia M, Al-Ahmady Z, Muller J, Fedutik Y, Ruis Aranzaes J, Antipov A, Kostarelos D, Astruc S, Moya E, Huusfeldt Larsen K, Savolainen K, Norppa H**

Finnish Institute of Occupational Health; Technical University of Denmark, National Food Institute, Sāborg, Denmark; University of Manchester, United Kingdom; Nanocyl SA, Sambreville, Belgium; PlasmaChem GmbH, Berlin, Germany ; Université de Bordeaux, Talence, France; CIC biomaGUNE, Donostia, Spain.

15:15 **2-B.3**

Physicochemical Testing Strategies Towards Safer by Design Justification

Costa AL, Ortelli S, Blosi M, Baldisserri C, Viale L, Brunelli A, Badetti E, Bonetto A, Hristozov D, Marcomini A, Gardini D

CNR-ISTEC, Institute of Science and Technology for Ceramics – National Research Council of Italy, Via Granarolo 64, I-48018 Faenza (RA), Italy; DAIS - Dept. of Environmental Sciences, Informatics and Statistics, University Ca' Foscari Venice, Via delle Industrie 21/8 c/o INCA - VEGAPARK, I-30175 Marghera (VE)

15:30 **2-B.4**

Read Across and SAR: Methods increasingly used to evaluate the toxicological risks of emerging chemicals and technologies.

Lewandowski TA, Rice JR, Cohen JM

Gradient

15:45 **2-B.5**

Increasing Awareness among U.S. Construction Workers about the Risks of Working with Nano-enabled Products

Lippy BE, West GH

CPWR - The Center for Construction Research and Training

14:45 - 16:00

2-C

Synthetic Biology for Zika Virus and Other Applications

Chair: Gina Lane

Aula Magna

14:45 **2-C.1**

Effects of Secondary Vaccine Risks on Appraisals of Dengue Fever

Cummings CL, Tan SJ, Lim HY, Tan LL, Detenber B

Nanyang Technological University

15:00 **2-C.2**

The Politics of Fear and Loathing: Media Coverage of Ebola and Zika Cases in the United States

*Lane G, Sperry E**

William Jewell College

15:15 **2-C.3**

Zika and Communicating Risk

Hallsby AT

North Carolina State University

Parallel Session 3

16:30 - 17:45

3-A
Sustainability and Lifecycle of Nano-enabled Products

Chair: Elena Semenzin

Sala Goldoni

16:30 **3-A.1**

Assessing sustainability of nano-enabled products through the life cycle

Semenzin E, Subramanian V, Zabeo A, Pizzol L, Habicht J, Saling P, Wohlleben W, Ligthart T, Steinfeldt M, Malsch I

Ca'Foscari University Venice, BASF SE, TNO, University of Bremen, Malsch Technovaluation, University of Limerick

16:45 **3-A.2**

New Carbon Capture, Converted in Electricity (CCCE) technology by (UCnF) Reinforced Shape Memory Polymers-(SMPs) Nanostrip Multilayers

Olaru P

SETEC-University POLITEHNICA Bucharest-Romania

17:00 **3-A.3**

12 Design Principles for 'Green Nano'

Steinfeldt M, von Gleich A

University of Bremen

17:15 **3-A.4**

Environmental Life Cycle Assessment for a Carbon Nanotube-Based Printed Electronic Sensor Platform

Chappell MA, Shih WS, Bledsoe JK, Cox C, Janzen S, Gibbons S, Patel R, Kennedy AJ, Brame JA, Brondum M

US Army ERDC

17:30 **3-A.5**

Probabilistic methods for nanomaterial exposure and risk modeling

Nowack B

Empa - Swiss Federal Laboratories for Materials Science and Technology

16:30 - 17:45

3-B
Governance for Synthetic Biology and Advanced Materials

Chair: Keith Hayes

Sala Canova

16:30 **3-B.1**

Advances for Integrated Risk, Environmental, Quality, and Safety Management Systems with EMS-ISO 14001 and Key Enabling Technologies

Pereira EG, Wu D, Lambert JH

University of the Chinese Academy of Sciences, University of Stockholm, University of Virginia

16:45 **3-B.2**

Project Complexity and Risk Governance in the Construction Industry with Key Enabling Technologies

Dikmen Toker I, Birgonul MT, Lambert JH

Middle East Technical University; University of Virginia

17:00 **3-B.3**

Probabilisitic risk assessment for a synthetic gene drive precursor

Hayes KR, Barry SC, Beebe N, Dambacher JM, De Barro P, Ferson S, Ford J, Foster S, Hosack GR, Peel D

CSIRO

17:15 **3-B.4**

Prevention-Based Governance for Synthetic Biology: A Thought Experiment

Malloy TF

UCLA School of Law

16:30 - 17:45

3-C
Late Breaking Session 1: Risk Governance of KETs

Chair: Bart Walhout

Aula Magna

16:30 **3-C.1**

Defining an Emerging Technology: Lessons from Regulating Unconventional Shale Gas Development in the United States and the European Union

Goldstein BD

University of Pittsburgh

16:45 **3-C.2**

Risk governance as institutional transformation: towards an integrative framework

Krom A, Walhout B

National Institute for Public Health and the Environment (RIVM)

17:00 **3-C.3**

Balancing innovation and risk management

Florin MV

EPFL (Ecole Polytechnique Fédérale de Lausanne)

17:15 **3-C.4**

Nano risk governance: The prescriptive and the descriptive or the devil is on the detail

Palma-Oliveira JBJM

University of Lisbon

Parallel Session 4

08:15 - 09:30

4-A
Case Studies in Governance and Management

Chair: Mark Chappell

Sala Goldoni

08:15 **4-A.1**
Assessing and Managing Risk using Synthetic Data
*Baiardi F, Tonelli F**
University of Pisa

08:30 **4-A.2**
Criticality of Communication in Building Nuclear Risk Perception and Safety Culture in the Nuclear Power (Energy) Sector as a Core Responsibility of Stakeholders
Khan K
University of Vienna

08:45 **4-A.3**
Risk Governance Framework for Aerospace and Defence Projects
Virine L
Intaver Institute Inc.

09:00 **4-A.4**
Compliance with confidence: fashioning risk governance policies in the face of uncertainty
Ferson S
University of Liverpool

08:15 - 09:30

4-B
Risk Management and Safer Design of Nanotechnology Products

Chair: Anna Costa

Sala Canova

08:15 **4-B.1**
The Efficiency of Existing Control Measures in Reducing Health and Safety Risks of Engineered Nanomaterials (ENMs)
Oksel CO, Subramanian V, Semenzin E, Ma CM, Hristozov D, Wang XW, Costa AC, Fransman W, Marcomini A, Wilkins T
University of Leeds

08:30 **4-B.2**
Risk management of nanomaterials in R&D labs: case studies using the safety approach of the Nanolab project
Boccuni F, Ferrante R, Iavicoli S, Porcari A, Lodato F, Beltram F, Pingue P, Sorba L, Piazza V, Gemmi M*
Laboratorio NEST - Scuola Normale Superiore

08:45 **4-B.3**
Controlling the human health and ecological risks of nano-enabled products through the life cycle
Subramanian V, Semenzin E, Zabeo A, Pizzol L, Fransman W, Wilkins T, Hristozov D, Marcomini A
Ca'Foscari University Venice, TNO, University of Leeds

09:00 **4-B.4**
On-line Real-time Characterisation of Nanoparticle Size Distribution Using a Self-calibrating Ultrasonic Probe
*Falola A, Wang XZ**
University of Leeds

08:15 - 09:30

4-C
Late Breaking Session 2: Synthetic Biology: Risks and Opportunities

Chair: Scott Ferson

Aula Magna

08:15 **4-C.1**
Commercial Synthetic Biology: Biosecurity in the Gene Synthesis Industry
Liss M, Rusch A, Graf M
Thermo Fisher Scientific GENEART GmbH

08:30 **4-C.2**
Synthetic biology and needs for risk governance
Vermeire TV
National Institue for Public Health and the Environment (RIVM)

08:45 **4-C.3**
Developing a Frame Work for Environmental Impact Assessment of Synthetic Biology
Perkins EJ, Eberly JO, Warner CM
US Army Engineer Research and Development Center

09:00 **4-C.4**
Contrasting Efficiency, Risk, and Resilience Approaches to Management
Seager TP
Arizona State University

Parallel Session 5

10:45 - 12:00

5-A
Regulatory Science and Risk Management

Chair: Mike Goodsite

Sala Goldoni

10:45 **5-A.1**

Safe-By-Design Implementation Approach in Production Systems

Alberto AR, Peixoto M, Farinha M, Cabral A, Rato R, Estrela M, Silva E

ISQ - Instituto de Soldadura e Qualidade, Taguspark - Oeiras, Av. Prof. Dr. Cavaco Silva, n.°33 2740-120 Porto Salvo, Portugal

11:00 **5-A.2**

Regulatory science and decisions under risk and uncertainty: Current trends and emerging strategic legal and institutional issues in risk regulatory approvals

Le Gal E

University of New England, Armidale

11:15 **5-A.3**

Regulatory Science and Risk Governance

Aoyagi M

National Institute for Environmental Studies

11:30 **5-A.4**

Inclusive resilience: A new approach to risk governance

Renn O

Institute for Adanced Sustainability Studies (IASS)

10:45 - 12:00

5-B
Case Studies in Medical Technologies and Emerging Materials

Chair: Adriele Prina-Mello

Sala Canova

10:45 **5-B.1**

3D printers in disaster areas: opportunities and risks

*Armas I, Ionescu R**

University of Bucharest

11:00 **5-B.2**

The need for adequate risk governance to combat the emerging threat of antibiotic resistance

Mennen MG, Lubben IM

National Institute for Public Health and the Environment (RIVM), Bilthoven, the Netherlands

11:15 **5-B.3**

Mutistakeholders dialogues as a cooperative vigilance system

Browaeys DB

Paris 1 Pantheon Sorbonne Universiy

11:30 **5-B.4**

The Nanomedicine Translation Hub

Boisseau PM, Ceccaldi A

ETPN European Technology Platform on Nanomedicine

10:45 - 12:00

5-C
Late Breaking Session 3: Risk Governance of Nanotechnologies

Chair: Dong Chun Shin

Aula Magna

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Risk assessment of nanomaterials used in the EU food/feed chain

Schoonjans R

European Food Safety Authority

11:00 **5-C.2**

Is risk management on pace with innovation?

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Institute of Occupational Medicine

11:15 **5-C.3**

NanoStreeM: Strategies for Safety Assessment in Advanced Integrated Circuits Manufacturing

Prodanov D

EHS, IMEC, Kapeldreef 75, 3001 Leuven, Belgium

11:30 **5-C.4**

Exposure and toxicity assessment of manufactured and environmental Nano particles

Shin DC

Yonsei University, College of Medicine

11:45 **5-C.5**

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Universitat Polit

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Thursday, March 2, 2017

1-A.1

Prevention-Based Governance for Synthetic Biology: A Thought Experiment

Malloy TF
UCLA School of Law

Traditional risk assessment/risk management of potentially hazardous materials and activities has two primary features: development of acceptable risk levels and attainment of those levels through engineering and administrative controls. Comparative approaches approach risk as a relative matter, forgoing the use of absolute acceptable risk levels and evaluating instead whether alternative materials/activities may present less risk. One comparative approach, sometimes called prevention-based governance, places particular emphasis on identifying inherently safer alternatives which do not depend upon engineering or administrative controls to reduce risk. This presentation will engage in a thought experiment, applying a comparative governance approach to synthetic biology scenario. In particular, it will examine how the comparative approach (including methods for comparative assessment) can be applied in existing regulatory frameworks.

1-A.2

Risk Governance of emerging risks: An application of analytic-deliberative policy making

Benighaus L
Dialogik gGmbH

The detection of emerging risks is of fundamental importance for society. Unknown risks of tomorrow are hard to detect, let alone to manage. The presentation suggests criteria for detection emerging risks and introduces an integrated analytic framework for risk governance which provides guidance for the development of comprehensive assessment and management strategies to cope with risks, in particular at the global level. The framework integrates scientific, economic, social and cultural aspects and includes the effective engagement of stakeholders. The concept of risk governance comprises a broad picture of risk: not only does it include what has been termed 'risk management' or 'risk analysis, it also looks at how risk-related decision-making unfolds when a range of actors is involved, requiring co-ordination and possibly reconciliation between a profusion of roles, perspectives, goals and activities. The framework's risk process breaks down into three main phases: 'pre-assessment', 'appraisal', and 'management'. A further phase, comprising the 'characterisation' and 'evaluation' of risk, is placed between the appraisal and management phases and, depending on whether those charged with the assessment or those responsible for management are better equipped to perform the associated tasks, can be assigned to either of them.

1-A.3

Approaches to Risk Assessment for Nanomaterials in European Industry

Rickerby DG
European Commission, Directorate General Joint Research Centre

The increasing quantities of nanomaterials being produced necessitate an integrated approach to risk assessment and management. Inherent uncertainties and conflicting data on toxicological properties create distinct problems in identifying and quantifying the hazard. There are few reliable estimates of the amounts released into the environment, and insufficient knowledge regarding transport, transformation and accumulation. Conventional risk assessment methods have limited applicability to nanomaterials and, for this reason, several nano-specific risk assessment methodologies and tools have been developed. The aim of the present study was to examine attitudes to risk assessment of nanomaterials in European industry and to determine to what extent the available tools were actually used in practice. A questionnaire was circulated to producers of three of the most common types of nanomaterials – titanium dioxide, zinc oxide and carbon nanotubes – requesting information on risk assessment procedures. The size of the companies ranged from large international chemicals producers to small and medium sized enterprises. The information required included: number of workers employed in the manufacture of nanomaterials, total quantity of nanomaterials of each type produced, whether these nanomaterials were aggregated or dispersed, and details of the risk assessment procedures and tools used. The total amount of nanomaterials produced ranged from a few kilograms to more than a million tonnes per annum. Numbers of employees ranged from tens of thousands to fewer than ten but for the larger companies a relatively small percentage of workers were employed in nanomaterials production. Some form of risk assessment was carried out by approximately 60% of companies, including both routine and unintentional or accidental emissions. The majority of the respondents did not specify what tools were used to perform risk assessment or used existing internal methods. In only a single case was a nano-specific risk assessment method implemented.

1-A.4

Reframing Zika

Berube D, Hallsby GA, Hammond R, Adams M, Will R
North Carolina State University

The Zika virus (ZIKV) busted onto the public agenda in 2015 with an outbreak in Northern Brazil (Bahi and Rio Grande do Norte) and Colombia. We heard complaints about how this outbreak may impact the Olympics. Soon we began to see articles about a linkage between the ZIKV and microcephaly. By the beginning of 2016 Zika infections were reported in over 20 countries in Latin America and the Caribbean. The ZIKV moved toward Puerto Rico and finally the US mainland in southern Florida in 2016. Efforts to eradicate the vector, a subspecies of mosquito, involved not only traditional approaches but also some more radical ones. Three have surfaced as plausible including MosquitoMates bacterial approach (Wolbachia-infected Aedes), Oxitec's engineered mosquito ("Friendly Aedes aegypti Project"), and a set of others propelled by gene drive technology. For publics, they were all GMOs. This paper examines the conflation and attempts to tease framing theory to offer proponents of science and technological solutions to compelling issues directions to reframe their solution so they are more consistent

with public values. The team of authors from the PCOST (Public Communication of Science and Technology) at NCSU while writing a book the Communication of Zika and criticizing the greening of nanoscience began a dissection of framing theory as well as social movement reframing literature developing a toolset to unpack frames and develop new ones.

1-B.1

Imminent challenges for risk assessment of manufactured nanomaterials

Mattsson M0, Simkó M
SciProof International AB, Vaktpoststigen 4, 83132 Östersund, Sweden

Risk assessment (RA) of manufactured nanomaterials (MNM) is essential for regulatory purposes and risk management activities. Similar to RA of 'classical' chemicals, MNM RA requires knowledge about exposure as well as of hazard potential and dose response relationships. What makes MNM RA especially challenging is the multitude of materials (which is expected to increase substantially in the future), the complexity of MNM value chains and life cycles, the accompanying possible changes in material properties over time and in contact with various environmental and organismal milieus, and the difficulties to obtain proper exposure data and to consider the proper dose metric. The present specific tools used in characterization of MNM, in exposure assessment, in toxicological testing, and the risk assessment are appropriate, but not necessarily sufficient for RA. Methodological development in material characterization and detection, especially at low levels, better understanding of matrix interactions, improved understanding of tissue kinetics and effects of low level exposures, development of appropriate dose concepts, and development of quantitative RA will help decision makers when performing MNM relevant risk management. This presentation will furthermore stress the need to consider the entire value chain for performing RA, and not limit the assessment to a limited part of the life of a material.

1-B.2

Tool for the hazard assessment of nanomaterials focusing on realistic environmental conditions

Schlich K, Hund-Rinke K
Fraunhofer Institute for Molecular Biology and Applied Ecology

To mimic real environmental conditions model scenarios including exposure to chemicals as in sludge, effluents or runoffs are needed. The sewage sludge and soil microflora is responsible for degradation processes of e.g. organic chemicals. The protection of the microflora is extremely important, since it is responsible for the preservation of biogeochemical nutrient cycles. Within the EU project SUN (http://www.sun-fp7.eu/) a tool was developed addressing two essential microflora habitats (sewage sludge and soil). The OECD 303A was used to estimate the impact on the biological function of STPs and adapted for the adequate use in risk assessments of nanomaterials. An application technique for nanomaterials into the STP was developed, depending on their stability in media continuously via a tube system or in a stepwise approach as mixture with synthetic sewage. For the use of the STP as a quick tool for assessing the fate and effects of nanomaterials, the duration was adjusted to one complete sludge age of approximately 14 days. Besides fate of the nanomaterials via chemical analysis, the effect of the nanomaterials dosed into the STP was determined by observing the degradation activity of the sewage sludge microorganisms. The concentration of nitrate, nitrite and ammonia in the effluent of the different treatments was measured to investigate effects on denitrification or nitrification steps. In a last step the sewage sludge was dewatered and applied into soil. In long term tests the effect on ammonia oxidizing bacteria was determined over a test period of 140 days. The combination of a simulated process in STP with long term studies on the effects of various nanomaterials provides a good tool to determine both fate and effect of the nanomaterials in a STP and the terrestrial environment. The results for a pristine CuO-NM tested with the tool will be presented.

1-B.3

Next steps in environmental risk assessment of engineered nanomaterials considering material-specific properties

Wigger H, Nowack B
EMPA - Swiss Federal Laboratories for Materials Science and Technology

Engineered nanomaterials (ENM) are advocated due to their unique material properties and are consequently applied in products entering the market by having a high variety not only in terms of products but also regarding the applied forms of the materials, e.g. with respect to mineral phase or coating. In order to meet the required properties in applications, ENMs are specifically designed for a certain purpose. In the course of the last years, different environmental exposure assessment models and hazard testing strategies have been developed to identify potential environmental risks. In these current approaches, the exposure models have normally considered a "generic ENM" which makes a comparison with hazard data challenging in the risk characterization step.

This work investigated if it is possible to distinguish ENM flows in environmental exposure assessment models and if the different form shows a different adverse effect in hazard assessments. For some materials, the ENM flows can be separated into forms with different crystal structure that are used in different applications. An example would be photostable and photocatalytic TiO2 that have a different functionality and are thus used in different applications. We analyzed all major ENMs that have so far been investigated in material flow models for the potential to separate the flows. We have then evaluated if there are indications that the various forms have also different toxicities. By combining the separated flow modeling with a form-specific hazard modeling, we can obtain a risk characterization for specific forms of one ENM.

1-B.4

Probabilistic approach for assessing risk to infants from nano-enabled products

Pang CB, Hristozov D, Zabeo A, Pizzol L, Tsang MP, Sayre P, Marcomini A
Ca

Silver nanoparticles (n-Ag) are widely used in consumer products and many medical applications because of their unique antibacterial properties. Their use is raising concern about potential human exposures and health effects. Therefore, it is informative to assess the potential human health risks of n-Ag in order to ensure that nanotechnology-based consumer products are deployed in a safe and sustainable way. Even though toxicity studies clearly show the potential hazard of n-Ag, there have been few attempts to integrate hazard and exposure assessments to evaluate risks. The underlying reason for this is the difficulty in characterizing exposure and the lack of toxicity studies essential for human health risk assessment (HHRA). Such data gaps introduce significant uncertainty into the risk assessment process. This study uses probabilistic methods to assess the relative uncertainty and potential risks of n-Ag exposure to infants. In this paper, we estimate the risks for infants potentially exposed to n-Ag through drinking juice or milk from sippy cups or licking baby blankets containing n-Ag. We explicitly evaluate uncertainty and variability contained in available dose-response and exposure data in order to make the risk characterization process transparent. Our results showed that individual margin of exposures for oral exposure to sippy cups and baby blankets containing n-Ag exhibited minimal risk.

1-C.1

The role of perceived risk of genetic engineering (GE) on public support for the release of GE mosquitoes to reduce the spread of Zika virus

Lull RB, Brossard D, Hallman WK, Jamieson KH
University of Pennsylvania, University of Wisconsin-Madison, Rutgers University

After Zika virus spread throughout the Americas in 2015, the World Health Organization declared a Public Health Emergency, conveying the urgency of adopting measures to reduce exposure to Zika. One controversial measure is to suppress the disease vector, Aedes aegypti mosquitoes, by genetically engineering (GE) males to carry a 'self-limiting' gene that causes their offspring to die before maturing to adulthood. Although prior research has addressed public risk perceptions of the use of GE in food, agriculture, and medicine, there is limited research in contexts in which GE is one possible response to a public health threat. In May 2016, we conducted a nationally representative survey of the US population (N = 950) to address the question: would potentially affected populations be willing to accept GE mosquitoes as a method to control the public health threat posed by Zika? Regardless of how familiar participants reported they were with either GE or Zika virus, as GE risk perceptions (i.e., agreement with the statement 'GMOs are risky for society') increased, support for releasing GE mosquitoes to minimize the spread of Zika decreased. However, that relationship was moderated by concern about Zika spreading to where they live - the more participants were concerned about Zika, the less their GE risk perceptions influenced their support for releasing GE mosquitoes. This suggests that using GE mosquitoes as a method to reduce the threat of Zika is one circumstance under which people who would otherwise be reluctant to support GE may be willing to accept GE as a solution to a public health problem that might personally affect them. Our findings suggest that GE risk perceptions, insofar as they relate to support for public health interventions using GE, are not immutable. This finding is important given that many GE applications involve public health, such as GE insects as a response to vector-borne diseases. Implications for risk governance and public policy are discussed.

1-C.2

A Comparative Analysis of Variations in Synthetic Biology Regulation

Trump BD
US Army Corps of Engineers

The ability to alter, manipulate, and control cell expression has driven many scholars to hypothesize synthetic biology's potential benefits within fields ranging from medicine, to ethanol production, to insect population control. However, synthetic biology may also yield potential novel health risks. In this vein, considerations of how the technology may generate problems for biosecurity and biosafety require a measured response by regulators and policymakers. Normatively, to protect against uncertain technological risks associated with synthetic biology's biosecurity and biosafety concerns, policymakers and key stakeholders within a given country must engage in active governance of the field based upon their perceptions of how serious such risks actually are.

However, regulation and governance does not occur in a vacuum, where contextual factors such as with the country's risk culture (or the sum of local culture, politics, and institutions within a given government that influence governmental perception of risk and its ability to act against potential challenges and emerging risks) may influence how technologies are regulated in a unique and differing manner from one government to another. Synthetic biology is no exception to this rule, where individual governmental systems such as with the United States, the European Union, and Singapore have all adopted differing approaches to regulate and govern the process of synthetic biology development despite limited information regarding the technology's risks and hazards. This presentation seeks to discuss how various elements of risk culture may contribute to such variations in the regulation and governance of the three case countries above, and also provides a general discussion of how various elements of risk culture may continue to influence variations in regulatory decision making and reform in the future.

1-C.3

Disclosure of Open and Transparent Research Practices and Public Trust

Landrum AR, Hilgard J, Lull RB, Akin H, Jamieson KH
University of Pennsylvania

Public wariness of motives behind industry-funded research contributes to distrust of agricultural biotechnology organizations. So, too, do the negative perceptions some publics hold about agricultural biotechnology-specifically, genetically-modified organisms (GMOs).

We conducted a large, online experiment (N = 1097) to examine potential effects--on public trust--of hearing about organizations that are involved in GMO research engaging in open and transparent research practices.

We found that disclosure of the existence of open and transparent research practices increased the participant's trustworthiness ratings of university and corporate organizations involved with GMOs. The results underscore the value of openness and transparency for industry and university research bodies developing agricultural biotechnology.

1-C.4

Categorization of Advanced Materials and European Environmental Regulation

Hansen SF, Pelsy F, Broomfield M, Kobe A
Technical University of Denmark; Milieu Consulting; Ricardo Energy & Environment; European Commission DG Environment

Advanced engineering materials or just 'advanced materials' is one of six technologies that have been identified as 'Key Enabling Technologies' (KETs) by the European Commission. Here, we present one of the first efforts to systematically categorise, define and evaluate advanced materials in the context of their coverage by EU environmental legislation. Most of the categorisation schemes for advanced materials suggested in the literature provide a clear classification of the advanced material categories that they include although they differ substantially in regard to the number of included advanced material categories and the extent of coverage. A few schemes entail advanced material categories that are not defined or explained in any detail. In the context of regulatory coverage of advanced materials, it is particularly important to understand whether advanced materials or a specific category of advanced materials (e.g. nanomaterials and high-performance polymers) can be said to fall under definitions already set under EU legislation. For instance, the definition of polymers under REACH may not be adequate for high-performance polymers. A substantial effort is needed in order to ensure that definitions of advanced materials used in forthcoming research and regulation cover all relevant categories of advanced materials. Limited or no regulatory issues are foreseen if they do fall under existing definitions, whereas it is unclear how advanced materials will be regulated, if they do not fall under legislative definitions. Furthermore, a better overview is needed of the current annual manufacturing, production and commercialization of advanced materials in general and the different categories of advanced materials, to support regulation and an evaluation of environmental releases and potential risks. Further expert consultation and stakeholder engagement is needed in order to understand what the risks might be and how they might best be explored and handled.

2-A.1

The late incorporation of risk governance into nanotechnology policy in Brazil

Quevedo JP, Invernizzi N
Universidade Federal do Paraná

Nanotechnology entered the scientific agenda of industrialized countries since the beginning of 2000 and was funded with large public and private budgets. In the wake of science-society controversies around technological risks –e.g. the mad cow disease and genetically modified food, among others- science, technology and innovation (ST&I) policies to spur nanotechnology incorporated new strategies on risk governance along the development of this emerging technology. Brazil also incorporated nanotechnology as a strategic area of its ST&I policy. In a trajectory of stimulus to nanotechnology lasting more than 15 years, the governance of risk was left in second plan. The first action directed to environmental, health and safe risks issues was a call for research in 2004. However, this turned to be an isolated initiative, with no continuity. A similar call for research was planned for 2007, but never saw light. Then, only in 2011 the Ministry of ST&I launched a more systematic action, with the implementation of six research networks on nanotoxicology and two research networks on nano-instrumentation. In 2012, the country joined the consortium NANoREG, with a view to enlarge capabilities in risk and regulatory research. Some regulatory agencies started training their personnel on nanotechnology. However, at the same time, two bills were presented in Congress, one regarding labelling of nanoproducts and other regarding regulation of nanotechnology research and commercialization, but both were stagnant. Although late, an incipient and still fragile actor network is forming around the governance of nanotechnology risks. Based on contented analysis of official documents, registries of public hearings, news and interviews, this presentation aims to: a) identify, in the actions of Brazilian nanotechnology policy, the risk governance approach under construction; and b) examine the perspectives of Brazilian scientists regarding the legitimation of the research on nanotechnology risks.

2-A.2

Pitfalls of interdisciplinarity: finding common ground between nanorisk governance and nanoethics

Malsch I
Malsch TechnoValuation

The presentation raises some fundamental questions about incompatibility of the disciplinary cultures of experts in natural and social sciences and humanities concerned with nanorisk governance and nanoethics, respectively. In particular, natural sciences, and to a lesser extent social sciences, share a collective, cooperative mission to establish a common understanding of how the world in which we live is organised and functions. In contrast, humanities are characterised by competition between schools or traditions adhering to different interpretations of 'the meaning of life as we know it'. In the absence of an objective external reality, truth claims of each interpretation are corroborated by testing their internal coherence. In order to overcome relativism, dialogue is undertaken, aiming for a "fusion of horizons" between traditions (Gadamer, 1960). This incompatibility of disciplinary cultures constitutes a barrier to meaningful integration of traditional risk assessment and consideration of social and economic concerns, in order to support evidence-based and value-sensitive governance of nanomaterials. In this decision making process, decision support systems and ongoing dialogue fulfil complementary roles. In my presentation, I will propose a scenario for nanorisk governance making optimal use of a software decision support system such as the SUNDS (http://www.sun-fp7.eu) (c.f. Malsch et al, 2015) and broad stakeholder dialogue as in Nano2All: http://www.nano2all.eu. References: Gadamer, Hans Georg (1960) Wahrheit und Methode; Grundzüge einer philosophischen Hermeneutik Mohr, Tübingen [Truth and Method] Ineke Malsch, Vrishali Subramanian, Elena Semenzin, Danail Hristozov, Antonio Marcomini, Martin Mullins, Karena Hester, Eamonn McAlea, Finbarr Murphy, Syed A. M. Tofail. Empowering Citizens in International Governance of Nanotechnologies. In: Journal of Nanoparticle Research, May 2015, 17:215 (12 May 2015) http://link.springer.com/article/10.1007/s11051-015-3019-0

2-A.3

Reflections on EU projects SANOWORK and SUN; A Risk Management Perspective

Mullins M, Murphy F
University of Limerick

Reflections on EU projects in the Emerging Technology space: A Risk Management/T Perspective.

EU research consortia are by their nature multidisciplinary entities and a meeting place for distinct epistemic communities. Increasing emphasis on wider stakeholder impact, sustainability and on responsible business ensures that this intermingling of interests will continue. This paper reflects the experience of Risk Governance/Transfer academics within a number of large EU research consortia focused on developing safe and sustainable practices for the European Nanotechnology sector and in the fast developing field of automated driving. Risk governance is now seen as an important component of the area of emerging technology. Perhaps less understood however is the key role the insurance industry plays in underpinning the future of such sectors. The concept of uncertainty is implicit in the notion emerging technology. For stakeholders such as shareholders, workers, the public and the environment (afforded a legal personality in recent EU directives) this entails the taking on of a degree of risk. For those engaged in emerging technologies there is a need for a risk transfer mechanism to be in place in order to protect the interests of wider stakeholders. Insurance provides such as mechanism and is a key, albeit frequently overlooked, component in any risk control efforts. We discuss some of the issues pertaining to how research consortia might better communicate to the insurance sector and indeed leverage insights from that same community.

2-A.4

Developing Risk Radar for emerging risks in the area of nanotechnology/ engineered nanomaterials for the EU Project caLIBRAte

Jovanovic A, Ahmad M, Quintero FA, Markovic N
Steinbeis Advanced Risk Technologies GmbH

The emerging risks always pose the uncertain challenges and risks, mainly due to lack in their understanding and available past experience. In this case, a Risk Radar provides the necessary tool in order to fulfill the existing gaps and to provide a foundation for sophisticated/ systematic predictions and insights. The Risk Radar employ the concept of Horizon Scanning in the relevant domain initially developed during the EU Project iNTeg-Risk. Therefore, within the scope of caLIBRAte project, an interactive Risk Radar is under development focused on the nanotechnology and engineered nanomaterials. The Risk Radar provides the interactive maps based on the user-defined relevant search queries. The searched queries / articles are further classified and ranked automatically according to their "Relevance" and "Novelty" to the interested subject.

The Risk Radar that is being developed under the scope of caLIBRAte has added advantages for the industry, end-users, regulators, insurers and the wider research fraternity. This Risk Radar can also potentially interact with the decision making tools in the respective domains and the wider risk governance framework both developed and under-developing.

2-A.5

SUNDS, a decision support system for nanotechnology risk assessment & management based on multi attribute value theory

Zabeo A, Hristozov D, Semenzin E, Pizzol L, Subramanian V, Basei G, Marcomini A

Ca'Foscari University Venice

The SUN Decision Support system (SUNDS) web application software has been developed in the SUN European project on Sustainable Nanotechnologies (www.sun-fp7.eu). The software aims at supporting decisions on assessment & management of nanomaterials and nano-enabled products in industry, regulatory bodies and insurance companies. The proposed sustainability assessment applies a two tiers approach which, on the basis of the supplied information, is able to generate qualitative or quantitative results. Moreover, a certification standard questionnaire is present based on the CENARIOS certification standard. The first assessment tier is based on the Licara Nanoscan method which supports SMEs in assessing benefits and risks associated with new or existing nanoproducts. The second assessment tier is based on an adaptation of the authorisation process currently in operation within the EU REACH regulation. REACH is based on Risk control, demonstrating adequate control of risk due to a substance's use, and Socio-economic Assessment, demonstrating that benefits of using the substance significantly outweigh societal costs. The methodology developed in the software concerns the assessment of different sustainability aspects through the calculation of qualitative and quantitative results from the application of state of the art assessment methodologies. To face the substantial heterogeneity of information a Multi Attribute Value Theory specific assessment methodology is proposed which is intended to capture inputs relations and aggregate results by means of stakeholders' insights. The web application software has been mainly programmed in the ECMAScript 2016 programming language using the Meteor framework. Results are presented in a user friendly graphical user interface which makes widely use of dynamic charts. The software has been tested by the application to case studies including nano-copper oxide -based biocidal paint and plastic car bumper coloured with nano-organic pigment.

2-B.1

Review of Human Risk Assessment Models Considering Their Input Requirements and Applicability During Product Innovation Stage-Gates. First Results From Eu H2020 'Calibrate' Project

Oosterwijk T, Franken R, Fransman W, Dalmaso M, Poikkimaki M, Säämämem A, Stockmann-Juvala H, Kanerva T, Astrup Jensen K, Stierum R

TNO; Tampere University of Technology; Finnish Institute of Occupational Health; NCRWE

The EU H2020 caLIBRAte project aims to design, calibrate and implement a next generation systems-of-systems risk governance framework for manufactured nanomaterials (MNM). Aim of this framework is to allow for screening of existing and emerging risks, quantitative risk assessment for humans and the environment and implementation of safe-by-design decision support systems and risk management. A central part of the project is to support the assessment of MN along the "Cooper Stage-Gate®" product innovation model. An important part of this framework is concerned with human risk assessment models (WP2), in which integrated hazard, exposure and risk assessment models (HRA models) are being adopted and further developed for stage-gate specific requirements.

This talk describes the initial results of the identification of HRA models and proposal for refinement of these models based on stakeholder requirements at the different stage gates of innovation. The requirements involve general criteria, such as transparency of the model, operational costs, duration, capacity to deal with data gaps, compatibility of the model to accept new data etc.. More specific criteria for HRA models were also defined concerning both the model output and model input criteria. Secondly, existing human hazard, exposure and control banding and risk assessment models have been evaluated for their applicability towards the different stage gates of innovation bearing these predefined criteria in mind. Steps towards further refinement of the existing HRA models for application along the stage gate model as well as potential inclusion of novel approaches (e.g. physicochemical modelling, internal dose assessment and PBPK modelling systems toxicology, high throughput screening, adverse outcome pathway based approaches, bioinformatics) will be discussed.

2-B.2

Genotoxic hazard assessment of 31 nanomaterials in human bronchial epithelial cells

*Vales G, Catalán J, Correia M, Al-Ahmady Z, Muller J, Fedutik Y, Ruis Aranzaes J, Antipov A, Kostarelos,D Astruc, S Moya, E Huusfeldt Larsen, K Savolainen K, Norppa H**

Finnish Institute of Occupational Health; Technical University of Denmark, National Food Institute, Sãborg, Denmark; University of Manchester, United Kingdom; Nanocyl SA, Sambreville, Belgium; PlasmaChem GmbH, Berlin, Germany ; Université de Bordeaux, Talence, France; CIC biomaGUNE, Donostia, Spain

The possible carcinogenicity of engineered nanomaterials is one of the key questions in evaluating their hazard to human health. In vitro assays for genotoxicity are used to detect carcinogens that act through a primary genotoxic mechanism. We have assessed the genotoxicity of 31 nanomaterials in human bronchial epithelial BEAS-2B cells using the alkaline comet assay for the detection of primary DNA damage (24-h treatment) and the cytokinesis-block micronucleus assay (48-h treatment) to reveal chromosome damage. The nanomaterials tested included quantum dots, two sizes (3.5 nm and 20 nm) of gold nanoparticles (NPs), silver NPs, nanodiamonds, CuO NPs, TiO2 NPs and nanorods, and multiwalled carbon nanotubes (MWCNTs). All materials were studied in three different forms – with amino, carboxyl and polyethylene glycol functionalization. Only quantum dots were able to induce micronuclei with every surface functionalisation, suggesting that the effect was driven by the chemical composition of the nanomaterial. The 3.5-nm gold NPs induced DNA damage with amino- and PEG-functionalization and micronuclei with amino-functionalization. The 20-nm gold NPs produced DNA damage when amino-coated and micronuclei when PEG-coated. For silver NPs, the PEGylated form increased DNA damage and micronuclei and the carboxylated form micronuclei. Nanodiamonds were not genotoxic. Also an uncoated form was available for CuO, TiO2, and MWCNTs. Uncoated CuO and TiO2 NPs and TiO2 nanorods showed some genotoxicity in at least one of the assays used, while functionalisations tended to reduce or abolish the activity. Uncoated MWCNTs were not genotoxic, but carboxylated and amino-functionalized MWCNTs produced an equivocal result in the micronucleus and the comet assay, respectively. The amino-functionalized nanomaterials tended to be more cytotoxic than the other forms, which may have partly masked their possible genotoxic effects. [Supported by NMP4-LA-2013-309329 NANOSOLUTIONS]

2-B.3

Physicochemical Testing Strategies Towards Safer By Design Justification

Costa AL, Ortelli S, Blosi M, Baldisserri C, Viale L, Brunelli A, Badetti E, Bonetto A, Hristozov D, Marcomini A, Gardini D
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Understanding the mechanisms of nanomaterials (NMs) interactions with living systems and the environment is a fundamental key to assess toxicity of NMs [A. Nel, et al. Science 311 (2006) 622–627]. Establishing correlations between engineered nanoparticles (ENPs) physicochemical properties and main factors determining an (eco)tox positive response requires the colloidal characterization of nanomaterials, both in water and in (eco) tox relevant media, in order to better define their biological identity. CuO commercial nanopowder (PlasmaChem GmbH), used as the active component in the formulation of antimicrobial (preserving) wood coating, has been selected as a case study. Colloidal properties were quantitatively correlated to double-layer surface chemistry in order to provide information needed for the control of biological reactivity in a Safety by molecular Design approach (SbyD).

The effect that self-assembled monolayers of amphiphilic molecules (modifying agents) had on colloidal properties was assessed. The following modifying agents bearing different electric charge were used: positively charged polyethylenimine (PEI), negatively charged sodium citrate (CIT) and sodium ascorbate (ASC), and neutral polyvinylpyrrolidone (PVP).

The stability of colloidal CuO NPs systems in water, buffer phosphate and biological media have been fully investigated by determining zeta potential, mean particle size, fraction of dissolved copper and sedimentation rate.

An intelligent step-wise approach to support the correlation between materials intrinsic properties, their evolution in testing media, their relevance in recognized mode of actions, their biological reactivity as well as their technological functionality was provided at the final aim to justify the proposed Safer by Molecular Design solutions.

2-B.4

Read Across and SAR: Methods increasingly used to evaluate the toxicological risks of emerging chemicals and technologies

Lewandowski TA, Rice JR, Cohen JM
Gradient

An important requirement for emerging technologies is to limit inherent chemical hazard in order to address unforeseen exposure scenarios. Yet new chemicals or technologies may lack complete health effects data due to limitations on cost or time. Read-across methods are increasingly being used to address such data gaps. Two critical steps in a robust read-across methodology are 1) quantifying structural similarity between proposed surrogates and the target chemical, and 2) verifying an expected common mode of action (e.g. via structural alerts, high throughput assays). To better understand the utility of different analytical tools, we established two separate sets of chemicals with structural similarity to two targets of interest

2-B.5

Increasing Awareness among U.S. Construction Workers about the Risks of Working with Nano-enabled Products

Lippy BE, West GH
CPWR - The Center for Construction Research and Training

CPWR - The Center for Construction Research and Training has support from NIOSH to research the use of nano-enabled construction materials in the U.S. The Center maintains a web-based inventory of 545 products believed to contain engineered nanoparticles (ENPs). The extent to which nano-enabled construction products have been commercialized remains unclear, however, because no U.S. regulation requires manufacturers to identify engineered nanoparticles (ENPs) on labels or Safety Data Sheets (SDSs). Under OSHA's Hazard Communication Standard, manufacturers of nano-enabled products do not have to identify any component that represents less than one percent of the mix on a weight basis. Given the low mass of ENPs, OSHA's threshold may not be reached, allowing manufacturers to legally withhold information about nanoparticles. In 2008, Dr. Lippy presented findings at an EPA conference of an evaluation of 49 nano-SDSs. Only 6 percent provided cautionary language about using PELs or TLVs for the macro-sized materials. The author recommended that OSHA require all ENPs to be identified on SDSs and that conditional language be included advising against using PELs for the parent material. Lee et al. made similar recommendations about use of PELs in 2013 after evaluating 97 SDSs. They reported that 85% did not provide any nanomaterial-specific data. These authors developed a 2012 ISO technical report (ISO/TR 13329) that provides excellent guidance on preparing SDSs including identifying the nanoform components. CPWR surveyed 79 experienced construction tradespersons in 2013-2014 and found just over half were aware that nanotechnology has been applied to construction materials, but most did not know that nano-enabled products are commercially available in the USA. The European Trade Union Institute has developed training materials for workers. CPWR is working to fill this role in the U.S. by providing awareness training to union apprentice instructors and developing toolbox talks aimed at specific trades.

2-C.1

Effects of Secondary Vaccine Risks on Appraisals of Dengue Fever

Cummings CL, Tan SJ, Lim HY, Tan LL, Detenber B
Nanyang Technological University

This experimental study evaluates the influence of secondary risks on behavioral intentions to vaccinate against dengue fever. Secondary risks are novel potential harms caused from interventions taken to reduce initial primary risks "in this case evaluating secondary risks of vaccines as a response to the primary health risk of dengue fever. Informed by Protection Motivation Theory, this study experimentally assesses the role of communication regarding vaccine characteristics including vaccine effectiveness, likelihood of vaccine side effects, and vaccine production methods" whether it is communicated that the vaccine is created using synthetic biology. Results demonstrate that secondary risk in the form of the likelihood of side effects has significant influence on vaccine intentions and also alters perceived vulnerability to the dengue fever virus itself. This carryover effect from a secondary risk to new evaluations of a primary risk has significant implications for health communication initiatives that aim to improve patient and public understanding of viruses and vaccines. Vaccine production method was found to have no effect on intention and threat appraisal of dengue fever. These results provide new theoretical implications that suggest a possible extension to the existing Protection Motivation Theory, and offer practical implications for the manner by which governments and health authorities craft health messages pertaining to vaccines.

2-C.2

The Politics of Fear and Loathing: Media Coverage of Ebola and Zika Cases in the United States

*Lane G, Sperry E**
William Jewell College

This paper argues that attitudes of race, gender, and xenophobia influence perceptions of risk in disease outbreaks in the United States. Relying on Falguni Sheth's philosophical discussion of race, this paper examines how the media reporting of disease outbreaks, which on its face should be a "race-neutral" context, instead reveals how public reaction to those outbreaks is manipulated through socially constructed narratives of race. Sheth explains that the construction of race in a liberal political state, of which gender and ethnicity are key components, creates a means by which "populations are distinguished, divided and pitted against each other" (Sheth 4). This paper's application of Sheth's theoretical lens to media coverage of both the 2014 Ebola scare and the 2016 Zika Virus outbreak offers a means of understanding how public perception of the risks of contracting both diseases was manipulated by competing perceptions of racial identities of both victims and vectors.

2-C.3

Zika and Communicating Risk

Hallsby AT
North Carolina State University

This presentation offers a comparison of public risk messages of the 2014 Ebola crisis and the 2016 Zika epidemic. According to the availability heuristic, persons will likely anticipate risk based on relevant and related examples. My claim is that the ebola outbreak functioned as the "available" representative anecdote for explaining the Zika outbreak. Spaced only by two years, this presentation tracks the ebola- and zika-related messages offered by the CDC and regional public officials alongside public media coverage of each of the events. The objective is to identify specific differences, to identify moments when ebola functioned as a representative anecdote for Zika, and the ways in which risk messaging directed their audience to consider and compare related instances of threatened outbreak.

3-A.1

Assessing sustainability of nano-enabled products through the life cycle

Semenzin E, Subramanian V, Zabeo A, Pizzol L, Habicht J, Saling P, Wohlleben W, Ligthart T, Steinfeldt M, Malsch I
Ca' Foscari University Venice, BASF SE, TNO, University of Bremen, Malsch Technovaluation, University of Limerick

Clear operationalization and strategy for sustainable nanotechnology is just starting to be addressed. While development of safe products is pinpointed as a key element in the overall sustainability of nanotechnology, the inclusion of economic and social aspects of sustainability have also been emphasized by stakeholders. Apart from supporting individual stakeholders in developing more sustainable nano-enabled products, tools for risk management and sustainability tools are also envisioned in playing a role in nanotechnology risk governance.

In this context, in the frame of the SUN project, a sustainability assessment methodology was developed and implemented in the SUN Decision Support (SUNDS) system as one of the modules in its higher tier, named Socio Economic Assessment (SEA).

The SEA module compares scenarios of nano-enabled products to relevant alternatives with respect to their sustainability aspects (environmental, economic and social costs and benefits) through the lifecycle. The SEA methodology aims to pinpoint hotspots (i.e. high risks and impacts or low benefits) that allow the user to see in which ways the sustainability profile of a nano-enabled product can be improved. The unit of analysis is the scenario covering the whole life cycle of a nano-enabled product i.e. synthesis of functional components, product manufacturing, consumer use and product end of life (disposal, recycling and reuse). Within this scenario, the SEA module aims to account for salient sustainability aspects such as transformation of pristine nanomaterial to diverse nano-forms (which constitute different exposure agents), environmental (including human) targets, material and energy fluxes contributing to environmental impacts, economic inputs and social context.

3-A.2

New Carbon Capture, Converted in Electricity (CCCE) technology by (UCnF) Reinforced Shape Memory Polymers-(SMPs) Nanostrip Multilayers

Olaru P
SETEC-University POLITEHNICA Bucharest-Romania

New Carbon Capture, Converted in Electricity (CCCE) technology is essential to reduce global CO2 emissions. Large-scale adoption of classical CCUS technologies (for example, absorption, adsorption, and membrane separation) is currently limited by the additional energy requirements associated with CO2 capture, resulting in higher cost of energy and difficulties in transporting and sequestering the captured CO2 . Recently, CO2 capture has been demonstrated for mobile sources, capitalizing on the waste energy of combustion engines. Conversion of CO2 to useful chemicals and fuels is understood to be a requirement for the commercial success of any CCUS process but has proven to be very difficult because of the thermodynamic and kinetic stability of CO2. Our recently CO2 capture has been demonstrated for mobile sources capitalizing on the waste energy of combustion engines.

New Vyborcntmat-SMP (VycnT) is a nanostrip multilayer's pseudo-composite (SMP), with better conversion of CO2 to oxalates.The pseudo-composite / CO2 electrochemical cell has been proposed as a novel approach to capturing CO2 from mixed CO2 / O2 gas streams, particularly using Vyborcntmat-SMP(VycnT).This nanostrip multilayer's anodes of high-energy densities, demonstrated generate electrical energy for the cars.

These pseudo-composite / O2-CO2 electrochemical capture systems may be operated in either secondary (rechargeable) or primary (non-rechargeable) configurations. Results showed in a secondary cell, reduced CO2 species react with oxidized metal ions to form the metal carbonate or bicarbonate and electricity during cell discharge. Recharging the cell would ideally reverse the reaction, consuming electrical energy to release the captured CO2 and O2 and regenerate the metal anode. Adoption of these secondary electrochemical systems in a new CCCE process would therefore facilitate separation and concentration of CO2, as demonstrated.

3-A.3

12 Design Principles for 'Green Nano'

Steinfeldt M, von Gleich A
University of Bremen

The intention of many EU projects is the development of new tools for risk and sustainability assessment of nanotechnologies. One of the main goals of the SUN project was the development of an integrated SUN Decision Support System (SUNDS) based on nano-EHS data and methods and intended for practical use by industries and regulators. For SUNDS information and data are needed from toxicological and risk analysis and LCA. It can be used for the assessment of nanotechnology based products and processes in the design and production phases.

The development of materials, products and processes based on the next generation of functionalized nanomaterials is still

in an early phase of development. In view of the enormous knowledge problems with which prospective technology assessment is confronted, the importance of concurrent approaches to specific developments has to be emphasized. In early phases when applications and their contexts are still unknown, the focus must be laid on what is already known, the technology, the materials and their functionalities and, if already in view, the products and processes that are based on them. In order to realize the precautionary principle, criteria and guiding principles for the precautionary design of green resp. sustainable nanotechnologies, materials, products and processes are needed.

3-A.4

Environmental Life Cycle Assessment for a Carbon Nanotube-Based Printed Electronic Sensor Platform

Chappell MA, Shih WS, Bledsoe JK, Cox C, Janzen S, Gibbons S, Patel R, Kennedy AJ, Brame JA, Brondum M
US Army ERDC

Here, we describe efforts to characterize the potential environmental impact associated with the manufacture of a newly developed printed electronic temperature sensor using environmental life cycle assessment (Eco-LCA). The sensor is composed of a specialized carbon nanotube (CNT) formulation, called CNTRENE.

3-A.5

Probabilistic methods for nanomaterial exposure and risk modeling

Nowack B
Empa - Swiss Federal Laboratories for Materials Science and Technology

The current and future widespread usage of engineered nanomaterials (ENM) in industrial applications and consumer products will inevitably cause emissions of ENM to the environment and result in an increase of environmental exposure. As a starting point for an environmental risk assessment, exploring sources and pathways of release helps to identify relevant applications and situations where the environment may face exposure to ENM. This presentation shows how using probabilistic material flow modeling as basis, we can quantitatively identify exposure and risks by incorporating the uncertainty and variability in many of the model parameters. By combining the modeled exposure distributions with a probabilistic evaluation of environmental hazards, we can perform a full probabilistic environmental risk assessment of nanomaterials. This process has so far been performed for eight nanomaterials: nano-TiO2, nano-Ag, nano-ZnO, CNT, fullerenes, nano-Au, nano-SiO2 and nano-iron oxides. For these ENM the hazards in in water, soils and sediments were quantified using probabilistic Species Sensitivity Distributions (pSSDs) and compared to the predicted environmental concentrations (PECs). Predicted No Effect Concentrations (PNECs) were obtained from the pSSD and used to calculate risk characterization ratios (PEC/PNEC). For most materials and environmental compartments, exposure and effect concentrations were separated by several orders of magnitude. The probabilistic risk quantification allows us to consider the large variability of observed effects in different ecotoxicological studies and the uncertainty in modeled exposure concentrations. The risk characterization results presented in this work allow for a more focused investigation of environmental risks of nanomaterials by consideration of material/compartment combinations where the highest probability for risks exists.

3-B.1

Advances for Integrated Risk, Environmental, Quality, and Safety Management Systems with EMS-ISO 14001 and Key Enabling Technologies

Pereira EG, Wu D, Lambert JH
Independent Consultant ; University of the Chinese Academy of Sciencesl University of Stockholm; University of Virginia

To cope with the key enabling technologies calls for principled approaches to risk governance, risk communication, and systems analysis. Risk assessment addresses what can go wrong, what are the likelihood, and what are the consequences. Risk management addresses What can be done in what time frames, What are the tradeoffs among performance, costs, and risks, and What are the impacts of current decisions to future options. Risk communication builds on behavioral and social sciences and experience of practitioners. Integrated management systems for risk, safety, environmental, quality, and related programs address: What issues are in (and out of) the scope of the program, What are the allocations of program resources to time horizons, assets, organizational units, etc., and What are the processes for monitoring and evaluation of the program. n particular What are the continuous improvements added to the Plan-Do-Check-Act (PDCA)(1) cycle, which are a basis for management systems in ISO (1) standards. Such programs must systematically address emergent and future conditions across technologies, environment, behaviors, demographics, organizations, regulations, etc. This talk will review opportunities for advanced integration of the associated management systems, with focus on the challenges and opportunities presented since 2015 under the Environmental Management Systems (EMS) program, promoted through ISO 14001:2015, ISO 9001:2015 and others. Recent examples and experience from Europe, Asia, and the US will be shared. Recommendations for next steps in integration of similar management systems by industry, government and non-government agencies, and the military will be presented.

Acknowledgment: This effort was sponsored in part by the Univ. of the Chinese Academy of Sciences for a visiting professorship of Prof. Lambert at the UCAS in 2015-2017.

(1) International Organization for Standardization, http://www.iso.org/iso/home/standards/management-standards/iso14000.htm; accessed on: 14.09.2016

3-B.2

Project Complexity and Risk Governance in the Construction Industry with Key Enabling Technologies

Dikmen Toker I, Birgonul MT, Lambert JH
Middle East Technical University, University of Virginia

Multi-organisation construction projects are known to be high risk undertakings due to their technical, financial, social and organizational complexity as well as their vulnerabilities to external factors such as regulations, environment, behaviors, markets, innovations, etc. Adoption of the key enabling technologies (KETs), particularly in advanced automation, manufacturing, and materials, will bring this issue to the front. Thus, establishing an effective risk management system and a risk governance structure with the contribution of all parties (contractor, client, designer etc.) is critical to ensure project success with KETs. Evaluation and assessment of complexity as a part of risk management is helpful to the extent that risk events are driven or exacerbated by project complexity. In this paper, we will concentrate on the complexity assessment process for the context of risk management of KETs in the construction industry and propose a conceptual framework for project complexity assessment. Project complexities arise due to factors such as scale, time span, technology utilised, logistics, number of participants, multi-nationality, varying expectations of project stakeholders, financing models, contract types, environmental factors, country factors, public interest and project's impact on the environment, society etc. Utilisation of the KETs in the construction value chain creates a major source of technical complexity that should be evaluated, analysed and managed by the project participants. We will describe a case study of a large-scale health campus project to demonstrate emergence of risk events attributable to technological complexity and dynamic interrelations among various

risk-related factors and mitigation strategies. The case study will feature the proposed complexity assessment framework, and identify policy implications for an effective project risk governance structure.

3-B.3

Probabilisitic risk assessment for a synthetic gene drive precursor

Hayes KR, Barry SC, Beebe N, Dambacher JM, De Barro P, Ferson S, Ford J, Foster S, Hosack GR, Peel D
CSIRO

Synthetic gene drives may be a cost-effective way to control or eradicate agricultural pests, vector-borne diseases and invasive species. The US National Academy of Sciences recommends that the immediate and long-term benefits and harms of this new technology are addressed with robust, probabilistic risk assessment. This presentation discusses the methods and results of a probabilistic risk assessment for the hypothetical escape of mosquitoes that are modified to be male sterile by a Homing Endonuclease Gene (HEG) inserted on the X chromosome. This modification is the first stage in a development pathway of a new, powerful, synthetic gene-drive technology designed to eradicate malaria vectors in sub-Saharan Africa.

3-B.4

Prevention-Based Governance for Synthetic Biology: A Thought Experiment

Malloy TF
UCLA School of Law

Traditional risk assessment/risk management of potentially hazardous materials and activities has two primary features: development of acceptable risk levels and attainment of those levels through engineering and administrative controls. Comparative approaches approach risk as a relative matter, forgoing the use of absolute acceptable risk levels and evaluating instead whether alternative materials/activities may present less risk. One comparative approach, sometimes called prevention-based governance, places particular emphasis on identifying inherently safer alternatives which do not depend upon engineering or administrative controls to reduce risk. This presentation will engage in a thought experiment, applying a comparative governance approach to synthetic biology scenario. In particular, it will examine how the comparative approach (including methods for comparative assessment) can be applied in existing regulatory frameworks.

3-C.1

Defining an Emerging Technology: Lessons from Regulating Unconventional Shale Gas Development in the United States and the European Union

Goldstein BD
University of Pittsburgh

Characterization of a technological advance as an 'emerging technology' can be relatively straightforward for nanotechnology, cloning and similar recognizable scientific and technical breakthroughs. These inevitably bring public concern, questions about the need for regulatory oversight and the attention of toxic tort litigators. Characterization as an 'emerging technology' is more difficult when a relatively gradual string of multiple innovations leads to dramatic societal and/or economic breakthroughs. An example is unconventional gas development (UGD) in the United States which has significantly altered global supply chains, played a large role in US energy independence and dramatically dropped the price of natural gas. Industry has appropriately taken credit for technological advances, including hydrofracturing and lateral drilling techniques, allowing the exploitation of previously inaccessible deep underground shale gas. Yet UGD supporter's major response to public concern and to potential regulation is that hydraulic fracturing has been safely done for 65 years, seemingly contradicting the argument of a technological breakthrough. Compounding the uncertainties that are part of any new technology is that the scale of major potential positive and negative effects of UGD are local, national, regional and global. The local scale differs in the US as compared to the EU and elsewhere due to unique US private ownership of subsurface property rights which affects public acceptance of UGD. There are also EU/US differences in the role and effectiveness of NGOs, including the seeming unanimity of EU but not US NGOs in opposition to UGD, similar to the EU/US differences in NGO response to GMOs. Characterization of a technology as 'emerging' should take into account not only its pace and its uniqueness, but whether it has achieved a 'tipping point' in terms of social and economic impacts, and in public awareness in affected societies.

3-C.2

Risk governance as institutional transformation: towards an integrative framework

Krom A, Walhout B
National Institute for Public Health and the Environment (RIVM)

The central claim of this presentation will be that effective governance of risks and uncertainties associated with KETs requires institutional transformation. It will be argued that effective governance requires the development and organizational integration of a framework for RG with at least the following characteristics. First, it should provide actual guidance for action (through reflexive considerations that can be tailored to the case at hand). Second, the framework should connect and integrate (a) bottom-up experiences of practitioners and (b) more general insights, e.g. provided by political sciences or risk governance theories. Finally, it should inform organizational changes needed in order to be responsive to the relevant societal and institutional context (including, for instance, shifting responsibilities and societal expectations).

We will illustrate this by drawing from our experience in setting up a collaboration between the Dutch Ministry of Infrastructure and the Environment and the National Institute for Public Health and the Environment with regard to Risk Governance of New Technologies. The collaboration focuses on promoting Safe(r)-by-design with regard to nanomaterials and new biotechnologies (including gene drives and gene editing) that involves, among other things, close interaction with businesses.

From an historical perspective, Safe(r)-by-design can be regarded as the next step in approaches to risk governance, with more and more emphasis on participative processes. We will discuss opportunities this offers as well as challenges, particularly in terms of organizational changes needed in order to be responsive to the relevant societal and institutional context. Finally, we will suggest practical solutions, for instance for the incorporation of adequate checks and balances, and how to safeguard room for reflexivity and integration of relevant experiences into a shared framework for effective risk governance.

3-C.3

Balancing innovation and risk management

Florin MV
EPFL (Ecole Polytechnique Fédérale de Lausanne)

Technology must emerge, be encouraged and nurtured. It must not be unduly constrained. If regulators make too early decisions about them, they risk to miss opportunities and risks. If there are important risks and uncertainties, appropriate assessment must be done, in order to make informed decisions, and adaptive governance may be a right approach.

What is needed then is to make sense of new technologies by balancing opportunitie and risks. If society and policymakers are uncomfortable with the consequences of certain new technologies, it is a political choice that must be respected. But we need to help them understand the consequences of their decisions.

Communication between scientists and non-experts (whether in industry or policy) is thus a particularly important and challenging task. Each community has its own expertise, objectives and constraints. But we can work to bridge the gap, and create a favourable context for responsible and sustainable science, technology and innovation.

Reflecting insight gained in the work of the International Risk Governance Council the talk will illustrate that innovation management, risk management, policy and regulation are intrinsically linked and good innovation management requires good risk management. With its solid international network in risk governance and technology & public policy, and its multidisciplinary and multi-stakeholder approach, the IRGC has a well-established track record of building bridges between science, innovation and policy. It provides guidance about how to create supporting context conditions at public policy level, for the deployment of technology and innovation.

The talk will illustrate these concepts with examples of promising technologies whose development benefits from a risk governance approach.

3-C.4

Nano risk governance: The prescriptive and the descriptive or the devil is on the detail

Palma-Oliveira JBJM
University of Lisbon

There are several governance frameworks that are, in a more or less top down way, based in a global vision of agent.

4-A.1

Assessing and Managing Risk using Synthetic Data

*Baiardi F, Tonelli F**
University of Pisa

Risk has to be assessed and managed with no historical data anytime we adopt a new technology or a system that widely differs from the previous ones. Usually, this problem is solved by exploiting personal experience but the number of factors to be considered is so large that the output may be not objective and cannot be easily communicated.

Haruspex is a methodology that tackles the "risk with no data" problem by predicting the behavior of intelligent attackers against the system to be assessed. These attackers are intelligent and they minimize their efforts to control some predefined modules, their goal. It defines and executes the computer models of the system and those of the attackers to discover which agents reach their goals and how. Haruspex handles randomness through a Monte Carlo method and it returns a sample it builds by collecting data in multiple executions. The target system is modeled as a set of interconnected modules. The operations that a module defines are invoked by the modules that own the corresponding privileges. The module vulnerabilities enable some attacks, e.g. an action that returns some privileges an agent is not entitled to. An attack succeeds with a probability that depends on both the agent and further system properties. The model of an attacker describes goals, legal privileges, available information on the system and how it selects attack chains. An attacker exploits attack chains because one cannot reach a goal. A detailed modeling of chain selection influences the model accuracy.

The methodology is supported by the Haruspex suite, a set of tools to automate risk assessment and management. The suite tools build the models of interest, execute these models to produce a sample and use it to assess the risk and discover the most effective security investment.

Besides describing the framework and suite, we will present some assessments that have adopted the suite.

4-A.2

Criticality of Communication in Building Nuclear Risk Perception and Safety Culture in the Nuclear Power (Energy) Sector as a Core Responsibility of Stakeholders

Khan K
University of Vienna

Scientific and technological development has long been considered in the context of its associated risk to people and environment. Advancements in nuclear technology and continued expansion of its application in all major spheres of life such as health, agriculture, energy, industry, military and the outer space over more than half a century has tremendous effect on the social trends in the understanding and addressing the risk associated with it. The risk perceived generally differs from the specific risk associated with technology or technological development

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4-A.3

Risk Governance Framework for Aerospace and Defence Projects

Virine L
Intaver Institute Inc.

Aerospace and defence projects and programs are characterized by significant complexity, large cost, significant duration, and many risks. Moreover significant portion of these programs and projects are government contracts, which have additional project and risk management requirements. Aerospace and defence projects usually involve research and development components in the areas of new emerging technologies, which create new challenges for risk identification, analysis, and communication. This paper examines specific challenges related to risk analysis for aerospace and defence projects, as well as outlines government requirements in US and other countries with regards to risk analysis and risk management.

Risk analysis process for aerospace and defence projects has a number of specific features. Most project risks affect not only project schedules, but also safety, security, quality, etc. For example, bugs in on-board software for a space vehicle not only can delay a project, but can also present major safety and security challenges. It is important to identify and analyze all risk impacts at the same time as part of an enterprise risk management process using centralized risk register.

Since aerospace and defence projects and very costly and in many cases are financed from the public sources, the goal

is to create a process to ensure a risk resilience or ability to complete projects on time and on budget under many uncertainties. This involves mitigation and response planning as part of project scheduling as well as managing cost and duration of mitigation efforts. Also aerospace and defence projects include not only threats, but also opportunities, which could lead to cost saving and project acceleration.

Risk governance frameworks for aerospace and defence are established for a number of years and are good examples for other industries how risk analysis processes are implemented. The paper includes overview of NASA risk management process as an example of a risk governance framework.

4-A.4

Compliance with confidence: fashioning risk governance policies in the face of uncertainty

Ferson S
University of Liverpool

Sometimes policies and rules issued by regulatory authorities turn out to be self-defeating in that they induce undesirable behaviors within the regulated communities. We consider an example involving regulatory sampling guidance for occupational health and safety in the United States originally developed in the 1970s but still in use. This guidance presumes regulated industries collect measurements of workers' toxicant exposures compared against an occupational exposure limit. Because increasing sample size can only lead to a higher chance of exceeding this limit, no companies ever want to collect more than the minimum number of samples required. In practice, many companies are only required to collect a single sample measurement. These policies are hard to defend, yet precedent and fairness demand they continue to be used and applied to new factories and even to new industries where there may be a clear need for much wider data collection to demonstrate worker health and safety. We suggest that full accounting of uncertainty can encourage sampling beyond regulatory minima. Regulation should be consistent with risk analysis that distinguishes between variability and incertitude, and compliance determinations should take account of both. For example, when sample data are summarized as prediction intervals or probability boxes that inherently express both kinds of uncertainty, the breadth of incertitude narrows as more sample data are collected. The results can more clearly demonstrate compliance as the combined uncertainty decreases, even if some samples exceed the limit. We further suggest a tiered scheme dividing regulated entities according to the scrutiny they need, with tiers for compliant facilities, new facilities, and completely new industries, using outlier detection, equivalence testing, and tolerance analysis to show compliance.

4-B.1

The Efficiency of Existing Control Measures in Reducing Health and Safety Risks of Engineered Nanomaterials (ENMs)

Oksel CO, Subramanian V, Semenzin E, Ma CM, Hristozov D, Wang XW, Costa AC, Fransman W, Marcomini A, Wilkins T
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Despite the clear benefits that nanotechnology can bring to various sectors of industry, there are serious concerns about the potential safety risks associated with the production and use of ENMs, intensified by the limited understanding of how to ensure a safe working environment in nanotechnology-related applications. Clearly, there exists a need to expand conventional risk management practices to ensure safe production, handling and use of ENMs. Moreover, the performance of the existing risk management measures should be re-evaluated for ENMs since control options that are proven to be effective for mitigating risks associated with traditional particles might give unsatisfactory results in the case of nano-scale particles. To advance our understanding of the risk management approaches relevant for ENMs, this study has brought together the quantitative evidence on the technical and economic feasibility of traditional controls applicable for ENMs. A large amount of evaluative evidence on the level of protection offered by each control measures and the relative costs of their implementation has been collected through literature review and a specialised questionnaire survey participated by 36 nanotechnology organisations, which allowed us to propose a set of recommendations on safe handling and control of ENMs. The findings suggest that most relevant risk control options are based on isolating people from hazard through engineering measures (e.g. ventilation and chemical fume hoods) or personal protective equipment (PPE), rather than eliminating hazard at source. Although control measures related to the modification of ENMs have high efficiency in the occupational risk control hierarchy, they are currently not widely employed for ENMs since there is a high degree of uncertainty regarding the impact of manipulating nano-characteristics on the performance of final product. Clearly, more quantitative research is needed with respect to the efficiency and cost of each RMM to fully understand and compare their suitability in preventing risks associated with ENMs.

4-B.2

Risk management of nanomaterials in R&D labs: case studies using the safety approach of the Nanolab project

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The NanoLab project, funded by the Italian Workers Compensation Authority (INAIL), has developed novel tools for risk communication and safety management of nanomaterials in R&D laboratories, on the basis of a precautionary approach.

The project is focusing on three case studies (nanoparticles, graphene, nanowires) within the research labs of the partners, involving more than 500 researchers, in order to develop improved working practices for monitoring and handling of nanomaterials. A specific focus is the testing of existing control banding tools for risk assessment on nanomaterials, basing on the classification of the R&D processes, exposure monitoring on site, and comparative analysis of both literature and experimental data. This process led to the classification of risks related to nanomaterials for the different process steps of the three R&D case studies.

A web-platform, as well as specific labels, pictogram, safety sheets, have been developed to ensure appropriate communication of potential risks to R&D personnel and other operators working in the labs (such as inspectors, staff involved in maintenance and cleaning, guests, etc.).

The activities on the 3 case studies have been complemented by a mapping of R&I actors at national level potentially interested in the use of the Nanolab tools and methodologies.

During the presentation, final results of NanoLab will be presented, including a short demo of the Nanolab safety platform.

4-B.3

Controlling the human health and ecological risks of nano-enabled products through the life cycle

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While the global nanotechnology value chain is expected to reach $4.4 trillion by 2018 (1), and nanosafety research funding has been on a rise since 2005, large uncertainties about the environmental, health and safety (EHS) risks of nanomaterials (NM), including physicochemical characterization, environmental release, exposure and hazard estimation and risk characterisation, continue to persist (2).

In order to address these emerging issues, European Chemicals Agency (ECHA) has adopted a bottom-up approach in REACH implementation through two working groups (i.e. NanoMaterials Working Group and Group Assessing Already Registered Nanomaterials). The registration of the nano-form of chemicals has been mandated to be performed separately from the bulk form, and REACH guidance documents are being updated for NM (3). While ECHA's efforts and other activities may eventually lead to effective guidelines to control NM risks, there is a need to implement state-of-the-art risk control through the nano-enabled product lifecycle.

There are two key challenges to be addressed in implementing risk control through the nano-enabled product lifecycle. The first concerns the application of appropriate Technological Alternatives and Risk Management Measures (TARMM) to address the risk posed by a specific nano-form in an exposure context. The second concerns implementation of risk control in a cost effective manner, as even explicitly recognized by regulations (e.g. REACH Authorisation's Analysis of Alternatives and Socioeconomic Analysis) and policy prescriptions (e.g. European Commission's Precautionary Principle).

In this context, in the frame of the SUN project, a risk control methodology that addresses the issues highlighted above was developed and implemented in the SUN Decision Support (SUNDS) system as one of the modules, named Risk Control (RC), in its higher tier (4). The RC module supports the control of human health and ecological risks by assessing risk control strategies (so called TARMM) through nano-enabled product lifecycle (4,5).

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4-B.4

On-line Real-time Characterisation of Nanoparticle Size Distribution Using a Self-calibrating Ultrasonic Probe

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A novel design of ultrasonic probe is presented that allows fast online determination of particle size distribution (PSD) for nanoparticle processing in slurries. The software designed for the probe is equipped with 12 different ultrasound models and five powerful optimisation algorithms. The different ultrasonic model allows the estimation of PSD of system of various density contrast and wavelength regime. It is reported in this work that the probe can estimate the PSD of a particle system in less than one minute and is therefore useful for system where the PSD is changing rapidly and is also shown to give accurate PSD for concentrated system up to 50% by mass. An advantage of the probe, unlike the commercially available ultrasonic spectrometer, is it can self-calibrate new ultrasonic transducer which means the ultrasonic transducer can be replaced and the novel software has the capability to re-calibrate itself. Another advantage is the size of small size of the probe; it is only 12' long by .5' in diameter which is about the size of a temperature probe. In this work, PSDs of various particulate systems measured with the probe will be benchmarked against that measured by commercial particle sizing instruments. Applications of the prototype instrument to wet nano-milling of metal oxide materials will also be introduced.

4-C.1

Commercial Synthetic Biology: Biosecurity in the Gene Synthesis Industry

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DNA synthesis allows the direct construction of genetic material starting from digital information and raw chemicals. Improvements in synthesis technology are accelerating innovation across many areas of research, from breakthroughs in human health and medicine to the development of renewable energy, from agricultural productivity to the production of fine chemicals. Like any powerful technology, DNA synthesis has the potential to be purposefully misapplied and could give rise to both known and unforeseeable threats to our biological safety and security. In September of 2009, five of the world's leading gene synthesis companies came together to form the International Gene Synthesis Consortium (IGSC). By development and consequent application of a harmonized protocol for screening of the sequences of synthetic gene orders and the customers who place them, the IGSC companies aim to support government efforts to prevent the misuse of gene synthesis technologies.

4-C.2

Synthetic biology and needs for risk governance

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Three Scientific Committees of the European Commission (EC) published Scientific Opinions on synthetic biology that provide an operational definition, address risk assessment methodology, safety aspects, environmental risks, knowledge gaps and research priorities. The request for these opinions from the EC was motivated by the recognition that the introduction of synthetic biology entails uncertainties and potential risks that deserve scrutiny. The Opinions will contribute to the development of a risk governance approach for synthetic biology including aspects such as public and political acceptance and social, ethical, security and safety implications. The Opinions focus on safety and emphasize that advances in synthetic biology must be closely monitored to avoid potential problems affecting health, the environment and biodiversity. It is considered necessary to address alternative risk assessment methods.

Emerging technologies like synthetic biology increasingly seem to give rise to questions about the safety of their products, alongside questions on socio-economic issues, including ethical issues. When fundamental uncertainty exists on the risks and insights in (new) safety aspects are lagging behind the development of new technologies, appropriate legislation cannot be developed timely, public perceptions may be less favourable and innovation may slow down. This requires new approaches towards risk governance, including safe-by-design approaches, participative processes and public-private partnerships.

4-C.3

Developing a Frame Work for Environmental Impact Assessment of Synthetic Biology

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Rapid advances in Synthetic Biology have led to a great deal of excitement. The potential products and solutions promised by synthetic biology could fundamentally change many sectors, from energy and food production to health care and defense. Unlike conventional mechanical, electrical or chemical systems, which only work in the area they are administered, synthetic biology products, such as engineered organisms, can self-propagate in their environment. While significant resources are being devoted to developing these technologies, much less attention has been given on understanding the ramifications of these technologies on the environment, as evidenced by a recent National Academy of Science report that highlighted the uncertainty of releasing Gene-Drives into the environment. Existing regulations and risk tools for genetically modified organisms may be suitable, but the potential impacts of novel applications such as Gene-Drives are unknown. A comprehensive assessment of possible impacts associated with specific Synthetic Biology entities and functions as well as their potential interactions with the environment is needed. Here we present efforts to develop guidance to assess the potential environmental impacts of synthetic biology. The guidance includes input from technology developers and funding agencies, regulatory agencies, government and industry. Guidance in three principle areas are being developed: Needs for classification, risk tools, regulation of synthetic biology technologies; Approaches for quantifying environmental impacts of synthetic biology technologies; and tools for depicting risk, public concern, and ethical issues to support decision makers in using these technologies. There are a number of methods in development that can be implemented to track the fate, transfer and transferability of Synthetic Biology technologies, yet these may not be sufficient to ensure our security.

4-C.4

Contrasting Efficiency, Risk, and Resilience Approaches to Management

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While there is now widespread agreement that the proper perspective for thinking about problems of the environment is the product or material life cycle, the emergence of synthetic biology presents a serious challenge to the dominant tools of systemic environmental analysis: life cycle assessment (LCA). Originally developed for mature industries such as metals, chemicals, plastics, paper, and autos, LCA has recently been adapted to better suit the analytic needs of emerging technologies. Nevertheless, the principal data gathering methods of LCA rely upon the assumption that a distinct boundary between industrial and ecological systems can be drawn that allow compilation of an inventory of material and energy exchanges across that boundary. In the past, food systems have presented a challenge to definition of this boundary, because production clearly resides in both the industrial and the ecological domains. However, the paradigm of highly mechanized monoculture dominant in the US permits effective resolution of the farm as within the industrial, rather than ecologiocal. Synthetic biology obliterates the boundary, and calls for a new paradigm of analysis altogether. Fortunately, as an alternative to the toxicological, risk-based approach that has characterized LCA to date, a resilience-based approach to management of the synthetic biology life cycle offers promise. This presentation describes the three different ways of thinking about design, operation, and adaptation of technological systems. 1. Efficiency, which dominated the Industrial Revolution and is suitable for normal operations, 2. Risk, which characterizes the end of the Industrial Revolution and is suitable for unusual occurrences with estimable probabilities, and finally 3. Resilience, which is likely to be the analytic approach most appropriate for problem of the Information Age, and is suitable for those events outside observed or historical experience, but within the realm of possibility. Brief examples illustrate the contrast and applicability of these three paradigms.

5-A.1

Safe-By-Design Implementation Approach in Production Systems

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The Safe-by-Design concept has gained interest over recent years as it aims to reduce potential health and environmental risks at an early phase in the innovation process. The application of the Safe-by-Design concept in one technological innovation project allows the identification and management of uncertainties and potential risks, making it feasible. PROCETS “”PROtective composite Coatings via Electrodeposition & Thermal Spraying””, it’s an example of a technological innovation project, where the Safe-by-Design is applied, which takes advantage of the use of nanoparticles and nanostructured powders for production of composite coatings. These reveal better combination of properties when compared to those of hard chromium produced by electroplating or to WC-Co produced by thermal spray for the applications selected in the project. The main target of PROCETS is to deliver protective coatings covering a wide range of applications such as automotive, aerospace, metal-working, oil and gas and cutting tools industries by utilizing more environmental friendly materials and safer in relation to health compared to the currently used. This will allow the replacement of the hazardous process of hard chromium plating and WC-Co coatings via thermal. To achieve this goal, will be: 1) verify the compliance with standards of all project results, namely REACH, and defining the specific actions to direct the development activities toward the standards; 2) performed a risk management process following the principles and guidelines of the standard ISO 31000 and 31010; 3) performed a completed Life Cycle Assessment (LCA) analysis to define the energy and environmental profile of the new processes; 4) promote safe practices, based on the available information and literature, during electroplating and thermal spray coatings production (industrial scale), and identify the safer final products according to chemical and physical characterizations performed across the duration of the project. PROCETS is an European research project which started on January 1st, 2016, with an extent of 42 months, funded from Horizon 2020.

5-A.2

Regulatory science and decisions under risk and uncertainty: Current trends and emerging strategic legal and institutional issues in risk regulatory approvals

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When new products and technologies, such as new drugs, medical devices, pesticides, genetically modified organisms, as well as food, veterinary and other chemical products have been developed for the market, regulatory scientists who work for national public regulatory agencies have to decide on the basis of a highly scrutinised risk-informed (or evidence-based) and complex regulatory process whether or not they should release new potential health, safety and environmental risks to human and ecological systems. To make decisions under risk and uncertain in a complex surrounding legal and institutional environment, they follow risk assessment procedures and have take to take into consideration the precautionary principle, which is the legal prescription specifying the weight to be attached to uncertainty and possible impacts upon the environment. The best available scientific evidence on which they rely to make

their decisions can also be the subject to many political and legal controversies, as can be the processes that are used.

This paper intends to identify current trends and emerging strategic legal and institutional issues surrounding risk regulatory approvals processes, particularly as they relate to emerging agricultural biotechnologies. It goal is to contribute to the scholarship around legal, risk management, risk governance and compliance issues, particularly in the Australian context.

5-A.3
Regulatory Science and Risk Governance

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How science should build effective and meaningful relationship with various policy making agencies, especially environmental fields, whose policy making are currently requested to be risk-based, and evidence based way of making decisions? We begin discussion with categorization of science, risk governance, then science and regulatory policies to draw overview of science-policy interactions. For this following three points will be discussed in this paper. 1) The role of the science from the regulatory science point of view, with reference to post-normal science framework. 2) Risk governance and risk management from the policy making point of view. 3)regulatory science and policy making.

In conventional risk management scheme, risk communication is in charge of the risk issue that system is in charge. But recent risk events such as nuclear power plant in Fukushima show that this is not sufficient. Then the role of risk communication and policy making will be discussed. In conclusion, like IRGC stated, we need to categorize risk from simple to ambiguity, deploy precautionary principle, and take into account the public opinion. That is the social science version of regulatory science we need to effective risk governance and policy making.

5-A.4
Inclusive resilience: A new approach to risk governance

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The concept of resilience has been used in may disciplines for different notions of being able to respond adequately when the system is under stress. It has been widely applied in ecological research and denotes the resistance of natural ecosystems to cope with stressors (Holling, 1973; Walker et al., 2004). Resilience is focused on the ability and capacity of systems to resist shocks and to have the capability to deal and recover from threatening events (Carpenter et al., 2001; Rose, 2007). This idea of resistance and recovery can also be applied to social systems (Review in Norris et al., 2007; Adger et al., 2005). The main emphasis here is on organizational learning and institutional preparedness to cope with stress and disaster.

The governance framework suggested by the International Risk Governance Council (IRGC 2005) depicts resilience as a normative goal for risk management systems to deal with highly uncertain events or processes (surprises). It is seen as a property of risk-absorbing systems to withstand stress (objective resilience) but also the confidence of risk management actors to be able to master crisis situations (subjective resilience).

5-B.1
3D printers in disaster areas: opportunities and risks

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Disasters are complex events which create urgent needs in sometimes hard to reach locations. Response and recovery teams often face shortages of proper tools and are forced to wait long periods of time for these to be shipped to their site. One solution to this problem is the use of 3D printers. With them teams can print the appropriate tools for their particular intervention. As with other applications of 3D printing this role is also in its relative infancy. Yet if we are to expect increased use then we must also look at what opportunities will drive uptake and what environmental health and safety risks go with it. We discuss these issues in the context of less developed countries.

5-B.2
The need for adequate risk governance to combat the emerging threat of antibiotic resistance

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Antibiotic resistance (ABR) can be classified as a worldwide emerging threat, the costs and burden of disease of which will gradually rise to a huge extent in the coming decades. The most obvious threat now is carbapenem resistance (CPE), since carbapenems are last resort antibiotics and the ability to cure infections with this antibiotic becomes very limited. Combating the threat of ABR requires measures in different domains, e.g. reducing the use of antibiotics in human care and animal husbandry, adequate surveillance in humans, animals and environment, and improved cooperation between cure, care and public health institutions. Moreover, there is a need for alternative methods and means to treat infection diseases.

The risks related to AMR can be classified as ambiguous. The transmission of AMR can easily be underestimated. For long time, resistant bacteria can go unnoticed, while they also spread among healthy people. As a consequence, the threat is not easily and broadly recognized. The current measures against AMR follow the perspective of human medicine: screening, treatment and isolation of infected hospital patients. Future measures may be stricter give rise to ethical questions. Elevation of CPE may ask for long-term isolation and measures that go beyond the medical profession.

It was recently concluded that the health care system in the Netherlands lacks integrated care at some points. An integrated governance model to ensure a timely and integrated approach and yet guard proportionality of policy and measures is needed.

The RIVM proposes a strategy to combat ABR including a set of measures at different levels, an adequate surveillance system, an organizational structure and improvements for governance. The strategy will facilitate the complicated discussions about conflicting interests among health care professionals, scientists and policy makers, and address the need for national and international control.

5-B.3
Mutistakeholders dialogues as a cooperative vigilance system

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Emerging technologies require to consider risk uncertainties as irreducible. In this context, security and accountability in governance can only come from regular and sustained stakeholder dialogue.

Since 2013 in France, the NanoRESP Forum has achieved 12 dialogues dedicated to nanotechnologies.

The NanoRESP Forum demonstrates a new way of understanding knowledge and risk management.

The twelve sessions carried out since 2013 have addressed critical issues related to the characterization of nanoproducts, their unstable definitions, releases and their effects in the environment, and the need for new toxicology methods adapted to the original properties of nanosubstances.

They suggest several possible levels of progress, including:

- "safe by design" design, which integrates life cycle analysis and pollutant emissions into product design;

- Validation and standardization of methods for the characterization of final properties and toxicological characteristics of

nanomaterials and products containing them to validate the expected benefits of the innovation, precisely identify its potential effects and comply with regulations;

- improving information between producers, integrators, distributors, users / applicators and consumers in order to limit exposures to products capable of releasing nanoparticles;

- the organization of a collective and plural evaluation of products containing nanomaterials in order to prioritize the societal benefits of their marketing.

A new model for risk gouvernance

The Forum NanoRESP constitutes an original socio-technical experimentation. It innovates in hybridizing the registers : this does not resemble either the postures of observation of academic practices or the internal dialogues of stakeholders of companies or federations. The NanoRESP Forum seems to be a relevant support for an active and multi-actor governance of innovation.

5-B.4

The Nanomedicine Translation Hub

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ETPN European Technology Platform on Nanomedicine

Innovation in nanomedicine is mostly taking place in start-ups, SMEs and spin-off from academia. Entrepreneurs usually have an outstanding knowledge about their product, its characteristics, in properties, its impact in vitro or sometimes in vivo, because they are either at the origin of the technology or have joined the team who was at the origin. However these entrepreneurs start facing some major difficulties when translating their proof of concept towards the market. These difficulties are for instance in the ultra fine characterisation of their product and its scale up manufacturing in GMP grade. Besides young entrepreneurs are lacking coaching and mentoring on industrializing their vision, on developing their start-up, on making the right decision at the right time.

ETPN, the European Technology Platform on Nanomedicine, has encouraged in 2015 the submission of complementary proposals under H2020 Framework Programme tackling the limitations previously listed, under a single umbrella. The importance of this new Nanomedicine Translation Hub for the emerging industrial sector in nanomedicine has been recognised by the European public authorities. Subsequently, three European projects, completely in line with the Hub's concept, have been positively evaluated by the EC for funding under Horizon 2020, and are currently in the finalization stage of their EU grant agreements.

5-C.1

Risk assessment of nanomaterials used in the EU food/feed chain

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Substances to be used in agri/food/feed products are subject to scientific risk evaluation. For Europe, it is the European Food Safety Authority (EFSA) that carries out the scientific risk assessment and the European Commission takes the decision based on all risk management considerations. The use of nano-sized particles in the food/feed chain is on the rise. Their physico-chemical properties, their potential hazards and the potential risks of their use are assessed by EFSA.

EFSA published in 2011 a guidance document on how to address human health risks. Until today, however, not many full safety assessments for nanomaterials in agri/food/feed are completed and the availability of data and standardised test methods is still poor. EFSA has identified four priorities for further guidance: advancements in physico-chemical characterisation of nanomaterial in complex matrices, best practice for ADME studies, experiences with toxicological studies and implementation of new legal requirements. EFSA is currently updating its existing guidance and will develop Environmental Risk Assessment Guidance to cover also the environmental fate and impact of e.g. nanopesticides and nanoformulations. The purpose is to help stakeholders and risk assessors in the Member States to prepare authorisation dossiers and ultimately to help protect the consumers' safety.

These activities will be carried out by a group of experts and based on the knowledge generated by e.g. European Research projects (e.g. NanoReg, NanoDefine, NanoLyse, NanoFate), the OECD working group for nanomaterials, and relevant research as reported by the EFSA Nano Network.

5-C.2

Is risk management on pace with innovation?

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Emerging technology can present a unique challenge for risk governance in cases where assessment capabilities for novel entities created by the technology are evolving in parallel with the applications of the technology. These cases where new uses are on pace with assessment methods can raise concern that products will enter markets faster than the development of risk management capabilities suitable for them. The concerns can then feedback to innovation pathways through over-regulation and consumer and investor avoidance, even when assessment methods are available and risks are avoidable. The particular challenge for the rapid pace of emerging technology that can occur now is that the knowledge of overlaps and gaps between new products and appropriate methods resides in the experts creating them. Products can be either unsafely introduced to markets or inappropriately rejected from development pathways simply through a lack of connecting knowledge of products with knowledge of methods. Therefore, so that risk uncertainty does not impede innovation of beneficial technologies, risk governance policies should be informed by the likelihoods of specific kinds of nanomaterials being used in products and the utility of methods to assess them in risk management decisions. To understand where gaps and challenges are for risk management, the Horizon 2020 ProSafe project investigated the future of risk management by completing a foresight exercise. This was implemented through a structured Delphi Forum across stakeholder groups to clarify consensus and divergence within the nanotechnology community. The forum consisted of an online Delphi poll that included invitation to over 2500 experts, followed by an expert panel held at the 2015 annual meeting for the Society for Risk Analysis in Washington DC, and finally a second online Delphi poll. This session will summarise the findings of the Delphi Forum, including the views of the nanotechnology community on the state and pace of risk management within the field and its applications.

5-C.3

NanoStreeM: Strategies for Safety Assessment in Advanced Integrated Circuits Manufacturing

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Nanoelectronics has a huge transformative potential for the society. The pace of innovation is very fast bringing a variety of new materials functionalized at the nanoscale into everyday life. New materials, including variety of nanoparticles are constantly introduced in the development of advanced technology nodes. This is recognized as a shared concern by the industry; therefore a number of smaller scale targeted process safety and occupational health monitoring campaigns have been conducted.

Understanding properties of engineered materials and how they affect biological systems, human health, and the environment is a relatively new area of scientific study which requires long term efforts. Timelines of obtaining better scientific understanding greatly mismatch those of product innovation and market distribution. Such a situation presents a challenge for both mitigation

of the occupational and environmental risks and the overall risk governance and policymaking. As a step in the direction of addressing this challenge 14 industrial and academic institutions from 6 EU member states initiated a collaborative project named NanoStreeM, funded under Horizon 2020 EU Framework Program for Research and Innovation. The overall objectives of the project are

(i) to build inventories of materials, research topics and directions relevant for nanomaterial use and exposure in nano-electronics manufacturing

(ii) to identify gaps in knowledge and methodologies to assess the risk of engineered nanomaterials used in semiconductor manufacturing or incidentally released as by-products of the manufacturing process

(iii) to apply obtained results for better training, management and governance of the risks related to engineered nanomaterials and industrial processes

The current phase of the project focuses on establishing trajectories of nanomaterials in semiconductor production facilities, identifying operations of concern and air sampling techniques suitable for demonstration of nanoparticle emissions in clean rooms.

5-C.4

Exposure and toxicity assessment of manufactured and environmental Nano particles

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The aim of this study was to investigate the exposure and its toxic effect of nano particles. To characterize the size distribution and chemical concentrations, the PM samples were collected by a 10-stage Micro-Orifice Uniform Deposit Impactor (MOUDI) from nearby traffic in Seoul. The PM size distributions were bi-modal, peaking at 0.18-0.32 and 1.8-3.2 um. The mass concentrations of the metals for fine particles (0.1-1.8um) accounted for 45.6-80.4% of those in PM10. The mass proportions of fine particles to PM10 for Pb (80.4%), Cd (69.0%), and Cr (63.8%) which can be related to traffic were higher than other metals. We observed PM concentration-dependent cytotoxic effects in BEAS-2B cells. We found that exposure to PM2.5 and PM10 from nearby traffic area induced significant increases in gene expression of inflammatory cytokines (IL-6 and IL-8). The cell death rate and release of cytokines in response to the PM2.5 treatment were higher than those of the PM10. The combined results support the hypothesis that ultrafine particles which contain nano-sized particles from vehicle sources can induce inflammatory response causing respiratory injury and cardiovascular injury as well.

And for manufactured nano particle, the toxicity of Ag and carbon nanotube was tested. BEAS-2B cell viability decreased with increasing doses of Ag (diameters : 40~70 and 100 nm) and MWCNT (diameters : 4~6 and 10~15 nm) nano-materials. At the higher exposure (>200 ug/ml), all materials induced significant cell damage. Nano Ag materials increased apoptosis and cytokine expression (IL-6 and IL-8) when over 100 ug/ml concentration. All MWCNTs weakly increased apoptosis and did not significantly increased cytokine expression.

5-C.5

A New Microbiological Risk Analysis Tool for Cryptosporidium to Support Decision Making in Drinking Water Treatment Plants

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One of the main hazards over the water quality in the water supply systems from surface raw water is cryptosporidium, considered by World Health Organization, as the most dangerous emergent pathogen. Analitycal methods for cryptosporidium are expensive, laborious and they do not have enough precission, on the other hand, labs analyze discretal samples, while drinking water production is a continuous process. In that point, the introduction of risk models in necessary to check the ability of safety of the water produced. The advances in tools able to quantify risk applied to conventional treatment drinking water treatment plants is quite useful for the operators, able to assess about decisions in operation and in investments. The model is applied into a real facility. With the results, it's possible to conclude interesting guidelines and policies about improving plant's operation mode. The main conclusion is that conventional treatment is able to work as effective barrier against cryptosporidium, but it is necessary to assess the risk of the plant while it is operating. Taking into account limitations of knowledge, risk estimation can rise non tolerable levels. In that situation, the plant must make investments in the treatment improving the operation, to get tolerable risk levels.

P.1

Risk assessment applied to the safe design of new pilot plants for the manufacturing of nano-enabled products for the European industry

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The pilot plants are H2020 ambitious instruments conceived by the EC for the strategic deployment of nanotechnologies. They can bridge the gap between nanotechnology research and markets, overcome acceptance barriers, convince potential end-users, facilitate large scale market introduction of new safe and sustainable nano-enabled products (NEPs) and ultimately, demonstrate the overall feasibility and competitiveness of new NEPs and production technologies. Project Platform (GA 646307) is a H2020 initiative aimed to develop three new pilot plants (PPPs) for manufacturing and commercializing CNT-nano-enabled products, for the European aeronautics and automotive industries. The design and construction of new PPPs, in compliance with the relevant Essential Health and Safety Requirements (EHSRs) of the Machinery Directive – the EU regulatory framework for new machinery - represents a project major challenge in the current scenario of uncertainty about risks from nanotechnologies. This paper focusses on the systematic and iterative approach for risk assessment and risk reduction followed by project Platform to achieve safe designs for PPPs. The risk assessment process has been conducted, mainly according to harmonized standard EN ISO 12100, taking into account the relevant phases of machinery life cycle, expected uses and operation modes of new PPPs. In addition, a specific tool to structure and document the risk assessment process – Platform toolkit - has been produced by the project.

P.2

The National Risk Assessment in the Netherlands: risks and benefits of new technologies for adequate capability planning

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Disasters and threats may cause serious disruption of society potentially affecting health, welfare, nature, environment, economy, critical infrastructure, the financial and government system and societal values. In order to prevent or minimize disruptive effects, the Netherlands apply an All Hazard National Safety and Security Strategy.

Potential risks, threats and hazards varying from floods, infection diseases and technical incidents to terrorism, cyber threats, organized crime as well as disruptive effects of new technologies, are analyzed using a methodology called the National Risk Assessment (NRA). In this methodology threats and hazards are assessed in terms of likelihood and impact using a uniform scoring method and are therefore rendered comparable. The impact criteria reflect the different vital interests of our society.

On the basis of the NRA, a capability analysis is performed to assess whether the country has sufficient capabilities to adequately deal with the risks and threats, and to determine which capabilities should be strengthened or developed. Capabilities can be technical measures, skills as well as legislation, resilience of civil society, and risk awareness. New technologies can also help in strengthening certain capabilities.

Assessment of the societal impact of risks and threats including the effects of new technologies is a main problem in the risk and capability analysis. How will society including politicians, policy makers, civilians, societal communities and business react on new technologies, once the pros and cons are manifest and possible disruptive effects are evident? Better insight and understanding of the perception, uncertainties, human manageability and expected behavior is necessary to adequately prepare society as well as to determine adequate governance arrangements to deal with such risks.

In this presentation, these issues are evaluated and discussed against the background our National Security Strategy.

P.3

Potential environmental impact of 3D printing technologies and its value chains

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This contribution investigates the potential environmental effects associated with 3D printing or its synonyms like additive or generative fabrication with the method of Life Cycle Assessment (LCA). Having identified gaps in current research, we conduct two explorative case studies, assessing changes in logistics resulting from the application of 3D printers and attended changes in value chains, and using comparative analyses of the environmental impact of various combinations of manufacturing processes and value chains. The first example addresses the manufacturing of consumer goods, specifically the cell phone case or "shell". The second case models the commercial application of 3D printing in technologically as well as logistically challenging value chain networks, here, the manufacturing of an aircraft spare part. Our research is guided by two questions: How can the environmental impact of existing products be altered by applying additive manufacturing processes, and which effects will most strongly influence the result of the LCA of additive manufacturing processes?

P.4

Life Cycle Thinking of Nanotechnology Based Applications

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As part of the EU FP7 SUN project, we implement the life cycle perspective in the SUN case studies. In order to assess potential environmental hot spot releases and environmental lifecycle impacts, the life cycle assessment (LCA) methodology has been applied and the results have been compared to conventional products with similar uses and functionality.

The project SUN has selected and has investigated the specific nanomaterials and associated products during the life cycle of the products (preproduction, production, use phase, end-of-life and recycling phases (re-use, recycling and/or final treatment and disposal) in different case studies (CS).

P.5

Alternative Assessment and Hazard Evaluation Approaches for Emerging Environmental Concerns: A Case Study of Refrigerants in Domestic Refrigerators

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Gradient

Concerns about global climate change have lead to phasing out the use of hydrofluorocarbons as refrigerants and propellants in many products. 1,1,1,2-tetrafluorethane (R-134a), the main refrigerant used in US household refrigerators, has an estimated global warming potential (GWP) 1,300 times that of carbon dioxide [CO2]). In the countries of the European Union, hydrocarbons are used for this application and have the benefit of low GWP at the cost of an increased flammability hazard. Replacing R-134a in US domestic refrigeration will likely require trade-offs, and the expanding methodology of Alternative Assessment (AA) can be used to evaluate the possible trade-offs of using various alternatives, chemical and otherwise, to R-134a. To test how an AA for this application might work, we conducted a Level 1 AA following the methodology of the Interstate Chemicals Clearinghouse. We compared five possible alternatives to R-134a: propane, isobutane, ammonia, CO2, and tetrafluoropropene (R-1234yf). We evaluated human health, ecological and physical hazards using GreenScreen

P.6

Hot Spot Release Mapping of Nanomaterials

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The development of nanomaterials especially of the next functionalized generation is still in an early phase of development. In these early phases, we are confronted with the Collingridge dilemma between far reaching design options on the one hand and a very limited availability of reliable knowledge about expectable impacts (Collingridge 1980). When products, processes, applications and their contexts are still unknown or uncertain the assessment must focus on what is already knowable, this is the character of the technology, of the materials and their functionalities and the intended applications based on them. The characterization of the materials and their functionalities offers information about hazard and exposure potentials (e.g. mobility in the environment, persistence etc.).

Based on this information the contribution will present a preliminary visual exposure assessment method. The tool integrates expert knowledge and literature data about release points and release quantities and extends the modeling approach to the entire life cycle of the nanoapplication.

Interviews of expert answers to questionnaires and literature survey build the basis for a detailed visualization of the life cycle stages of nanoapplications as well as for the weighting of release potentials. Based on this hot spots maps are created in which the environmental releases potentials are marked with an arrow and the weight of the flows corresponds with the thickness of the lines.

Thus the relevant nanospecific release potential can be easily identified along the life cycle stages of the nanoproduct and this knowledge may be used in the process of a precautionary product development and product use optimization. Some examples of hot spots release maps developed in the SUN project will be presented.

Collingridge, D (1980). The Social Control of Technology. St. Martin's Press. New York.

P.7

Releases from transparent blue automobile coatings containing nanoscale copper phthalocyanine and released fragments' effects on macrophages

Pang C, Neubauer N, Boyles M, Brown D, Hristozov D, Fernandes T, Stone V, Wohlleben W, Marcomini A
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Nanoscale copper phthalocyanine (n-CuPc) has been increasingly used in different products, including printing inks, coating

for automotive products, plastics, and textiles. Its use can improve the mechanical properties and add new features to the products, such as exhibit excellent transparency, lightfastness, heat stability, chemical and bleed resistance, processing capabilities and durability. It is estimated that Europe consumed an estimated 8 thousand metric tons of n-CuPc pigments (dry weight basis) in 2010. The automotive industry is the largest consumer of organic pigments, where increasing market requires stylish automobile coatings with vibrant colors "transparent blue" due to the pigments. The use of n-CuPc can potentially lead to a release of n-CuPc into the environment, especially during repairing the automobile. Environmental releases can pose high environmental and occupational risks, especially to auto mechanics performing car maintenance and repairs. Even though the automotive industry has risk management measures in place (local exhaust on the sanding equipment, face masks) to reduce occupational exposure, the knowledge on fate and hazard of sanding fragments is required for efficient risk management.

The aim of the study is to develop methods and to generate data to assess the exposure and toxicity of released n-CuPc in environment and human health. In order to achieve this, we measured the release of n-CuPc fragments from automobile coatings through a sanding approach, which is representative of repair processes. We investigated how the physicochemical properties of released fragments from a n-CuPc containing automobile coating change in environmental (freshwater) and biological (cell culture) media and identified the hazard of the released n Cu-Pc based on the macrophages mode.Given the increased use of n CuPc in automotive industry, assessing the toxicity of Frag n-CuPc using macrophage cells is important for future n-CuPc applications.

P.8

In Vitro Nanomaterial Safety Assessment: the NANoREG Outputs

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The partial understanding of the Environmental, Health and Safety (EHS) aspects of nanomaterials (NM) makes particularly difficult to frame them in a regulatory context. NANoREG project is aimed at the reduction of these uncertainties, linking answers needed by industry and regulators to questions on EHS aspects of NMs to a scientific evaluation of data and test methods.

P.9

THE RInnovaReNANO PROJECT

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The production and the use of nanomaterials (NMs) are tightly connected to their safety analysis and to a correct human and environment risk evaluation. Nanotechnologies and their safe and responsible development represent an ideal collaboration area, where research infrastructures can deliver tools and resources to the enterprises, especially the small and medium-sized enterprises (SMEs).

Lazio Region is characterized by a strong industrial presence, by an important institutional commitment (the Biosciences District) and by the presence of national research infrastructures, as the Italian National Institute of Health (ISS). Therefore, promote synergy among these realities could represent a fundamental tool to support regional technological competitiveness in the short-medium term.

ISS, due to its institutional mission, has developed competences and specific tools to deliver the necessary knowledges for NMs risk analysis and it is able to provide in-deep knowledge about approaches and operational scientific tools both from scientific and regulatory point of view.

In this frame, Lazio Region has funded the RInnovaReNano project to support the synergy among the regional innovative realities and ISS for a responsible development and a safe use of NMs. It is a pilot project aimed to deliver a useful contribution for a development of competences and scientific / technological capabilities of the Lazio enterprises, involved in research and innovation of NMs and nanotechnologies. Mostly, it will be realized a national web platform to provide and share with industrial and scientific community information related to the safety evaluation of NMs and the state of art of national and international research activities. Besides, the existing data and documentation produced by European Commission and other international institutions about NMs will be integrated.

This study is partially financed by Lazio Region, Prot. FILAS-RU-2014-1041

P.10

In vitro human digestion test to monitor the dissolution of silver nanoparticles

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Nanotechnology has revolutionized the food industry. In particular, the agro-food market has exploited the antimicrobial activity of silver nanoparticles (AgNPs) as food additives and food contact materials to extend the shelf life of consumer products. Since the human ingestion by voluntary and involuntary actions is possible, to get information on both effects of Ag nanoscale on health and identity of the molecular species arising from AgNPs biotransformation is fundamental. Within this context, our work aimed at studying the dissolution behaviour of AgNPs, simulating the human oral ingestion and the passage along the gastrointestinal tract. We implemented an in vitro test and provided a description of the bioaccessible ionic species by using a range of complementary analytical techniques. Our data indicated that dissolution of AgNPs is already complete at the stomach compartment, with 19% of released free ions and 81% digestive matrix-bound. Passing in the intestine, the resulting ions are mostly bound to the digestive matrix in an extent close to 98% (which probably could be excreted by feces). The other 2% is bioavailable for the duodenal translocation, and it could be possibly distributed, only in a low amount, through the blood circulation and the urinary tract. To confirm these preliminary observations, we extended the experimental plan with in vivo studies. We revealed that the major fraction of ingested silver is detected into the feces, whereas only a small portion of 2% bioavailable is found in blood and urine of mice (0.3% and 0.5%, respectively). Reasonable, the remaining bioavailable fraction (1.2%) is distributed in the tissues. Overall, these results show a correlation between the in vitro outcomes and the in vivo adsorption and make the dissolution test a promising analytical tool relevant for risk assessment of orally ingested nanoparticles and for regulatory oriented grouping.

P.11

A theoretical approach for predicting the mutagenic potential of nanomaterials throughout their lifecycle

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During the last few years, several theoretical models have been developed for assessing the potential risks of engineered nanomaterials. The final goal has usually been to identify safe exposure levels to which workers and consumers could be exposed without health consequences. This kind of quantitative approach is appropriate for most of the human toxicological endpoints considered in current regulations (e.g. REACH) but not applicable to endpoints without an identified effect-threshold - such as mutagenicity. The outcome of qualitative risk assessment is not a numerical limit but a statement (e.g. positive, negative or equivocal). Here, we propose a theoretical approach to assess the mutagenic potential of nanomaterial-enabled products throughout their lifecycle, which could be

incorporated into a web-based risk assessment tool. Following a 3-step hazard assessment strategy developed within the EU FP7 project GUIDEnano, we focus on describing the criteria for evaluating and weighting existing literature information based on current knowledge on the relevance and limitations of assays used in the genotoxicity and mutagenicity testing of nanomaterials. The similarity between the exposure relevant material and the tested one, and the quality of the study are checked using common algorithms developed in GUIDEnano for all types of (eco)toxicological endpoints. A third parameter, the relevance of the assay used, is specific for the mutagenicity endpoint. Different in vivo/in vitro studies and types of genotoxic effects are weighed to provide a final statement and to describe its associated uncertainty. We try to make use of all information available, including studies that do not comply with conventional test guidelines. Such a framework might help in developing more efficient screening strategies that avoid exhaustive testing of new nanomaterials (Funded by the EU FP7 GUIDEnano, Grant Agreement No.604387).

P.12

Integration into risk assessment of human omics data from in vitro studies

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The integration of existing knowledge to support the risk assessment of chemicals is still a challenge for scientists, risk assessors and risk managers. International initiatives like the Adverse Outcome Pathways (AOP) program have the role to support the integration of information from different sources and build collaborative platforms enabling the scientific community to address some of the risk assessment issues. However, the platform could benefit from further developments, which can perform e.g. a faster identification of existing background knowledge, data identification (including quality and completeness issues), identification of the kinetic and mechanistic models and the existing methods to address those, and finally support the appropriate dissemination of the outcomes. Within this case study, an integration of human in vitro transcriptomics data and modelling tools with the adverse outcome pathways (AOPs) is proposed, in order to identify areas of concern and support an evidence-driven risk assessment. Identification of eventual data and methodology gaps is also an objective of the present framework. Starting from omics in vitro human data, the approach includes the identification of relevant pathways, identification of analogue compounds and the verification versus specific AOPs. To quickly identify areas of concern, omics data represents a good starting point, since they show general adaptations of the cell to the exposure. The most relevant molecular pathways are selected and further analyzed for genes, diseases and chemicals associations followed by a connectivity mapping to genomic profiles of other compounds with similar modes-of-action. Further the cross checking of adverse effects versus specific AOP key events, using the information from the AOP-Knowledge Base is performed. This approach could support the risk assessment of individual or group of compounds starting from the transcriptomics profiles, identify data gaps and eventually propose additional testing.

P.13

NANOGECO - Paint nanoparticles generated by atomization spray. Risk evaluation.

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Nanomaterials are nowadays the great concern of scientists and are incorporated into many common products. Nanoparticles (NPs) are increasingly been added to paint and coating formulations to improve mechanical, physicochemical and antimicrobial properties. Spray painting is known to cause harmful effects due to the generation of nano-size particles during the spraying process. Inhalation is the major route of exposure to airborne NPs and their potential effects on the human heath (in particular on the deep lungs) remains unclear.

In this work, we report the characterization of the non-volatile fraction of paint overspray created by air spray guns. Different techniques were used as Centrifugal Liquid Sedimentation (CLS), Transmission Electron Microscopy (TEM), Scanning Electron Microscopy (SEM), Energy-dispersive X-ray spectroscopy (EDX) and Electrical Low Pressure Impactor (ELPI). Paints containing titanium dioxide (TiO2) or carbon black (CB) NPs were studied and aerosols were produced by using IWATA 1,3 mm gun (flow rate: 20 g /min). TEM confirms the presence of two kinds of droplets in the aerosol spray: microdroplets (1 µm to 10 &µm) and nanodroplets (100 nm to 1 µm). TiO2 NPs appear only in the form of agglomerates (average size: 460 nm) while individualized CB NPs are observed. In both cases, NPs are preferentially located inside microdroplets. Characterizations show that NPs seems strongly embedded into the polymer matrix, this means that different interactions as hydrogens bonds, electrostatic and Van Der Waals interactions may take place between the NPs and the polymer. The acute potential toxicity of the paint aerosol in a whole-body exposure model will be evaluated by histopathological examinations of mains organs on rats. Biopersistence will be evaluated using Particles Induced X-ray Emission (PIXE).

Finally, based on literature and experimental data, risk associated to nanodroplets produced by paint atomization will be determined.

P.14

Colloidal Characterization of Nano-sized Pigments in (Eco) Toxicological Media

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Engineered nanomaterials are embedded in different matrices, such as plastics, coatings and cosmetics. Nano-sized pigments are added to different consumer polymer-based products, such as polyethylene (PE), polypropylene (PP), polyethylene terephthalate (PET) etc., to give them color.1 The nanoparticulate structure enhances color fastness and persistence in application with respect to bulk material.2 However, the risk assessment of nanopigments is still a challenge, calling for an additional physico-chemical characterization. In this context, within the EU FP7 SUN project, the colloidal stability of organic nano-sized pigment PRED 254 and Fe203 pigment was investigated in biological and environmental media, relevant for (eco)toxicological testing. In particular, centrifugal separation analysis (CSA), combined with dynamic and electrophoretic light scattering (DLS and ELS) and Transient Resistive Pulse Sensing (TRPS) techniques, have been employed to assess the stability of the tested nano-dispersions. The colloidal characterization performed in the tested media may allow to correlate physicochemical properties of nano-sized pigments with principal factors determining the (eco)toxicological outcomes and estimate their behavior in real environments. The release of sub-micro fractions from nanocomposite materials (nanopigments embedded in a polymeric matrix) has also been investigated to estimate the possible exposure scenarios occurring at different life cycle stages.

P.15

Emerging Tools to Estimate and Predict Exposures to Chemicals

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The volume and variety of manufactured chemicals is increasing, though little is known about the risks associated with the frequency and extent of human exposure to most chemicals,especially newly synthesized chemicals. A simplified,

quantitative visual dashboard to explore exposures across chemical space will be demonstrated. Diverse data streams are integrated within the interface such that different exposure scenarios for "individual," "population," or "professional" time-use profiles can be interchanged to tailor exposure and quantitatively explore multi-chemical signatures of exposure, internalized dose (uptake), body burden, and elimination. This sytems, known as Ex Priori, can quantitatively extrapolate single-point estimates of both exposure and internal dose for multiple exposure scenarios, factors, products, and pathways. Currently, EPA is investigating its usefulness in life cycle analysis, insofar as its ability to enhance exposure factors used in calculating characterization factors for human health. The discussion will also address EPA's recently refined human exposure models, including SHEDS-HT and HEM.

P.16

Developing Collaboration for Risk Management: Examining Multilevel and Intersectoral Risk Communication

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Extreme weather risk management requires the collaboration of various levels of organizations and stakeholders: from meteorologists who master forecasts with high uncertainty, to local authorities who dispatch operational efforts, to citizens on the grounds who have terrain knowledge and can volunteer as 'zero-responders'. Across the timeline, from preparedness to recovery, mandates, knowledge and resources criss-cross in-between sectors. A socio-ecological model of governance requires sharing distributed knowledge for concerted multilevel response. Risk communication about hazard, vulnerability, impact, ripple and uncertainties must be activated pre-event across sectors to plan preparedness and mitigation. What are key features of communication in newly formed groups of diverse professionals in team tasks? What are the indicators of fruitful collaboration? First, a framework of collaborative risk management applicable to extreme weather risks is presented. Second, we designed a research and training procedure with an in-vivo simulation varying group composition and tasks. Then, our study examined interorganizational collaboration in a public communication task. Participants were emergency management officers, public servants and volunteers from different types of organizations and backgrounds. We rated their communication behaviors in terms of content and process: statements, queries, explanation, verification, anticipation, addition, control and engagement. We also examined externally-rated performance (decision quality) as well as self-reported satisfaction, team functioning, frustration, and trust. Regression analyses showed that performance related to engagement and generating alternatives. Frustration related more to process than outcome. Participation was linked to trust. Results are interpreted in view of a multilevel model of communication behaviors and of governance. We highlight the need to train for interdisciplinary intersectoral collaborative risk management.

P.17

NanoFASE Project: Nanomaterial Fate and Speciation in the Environment, towards an integrated exposure assessment framework

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Progress is needed in prediction of environmental distribution, concentration and form (speciation) of nanomaterials, to allow early assessment of potential environmental and human exposure and risks, facilitate safe product design and include these aspects in nano regulation. This challenge is addressed by NanoFASE- Nanomaterial Fate and Speciation in the Environment (Horizon 2020 n

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P.18

Protection Motivation and Communication through Nano-Food Labels: Improving predictive capabilities of Attitudes and Purchase Intentions toward Nano-Foods

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The development and use of nanotechnology applications in the food industry (nano-food) have been growing steadily in recent years. While visions for nano-food suggest that the applications will improve product quality and safety, they are also controversial for several reasons, including potential long-term human health risks coupled with difficulty in assessing low-dosage nanoparticle risks, as well as value-based objections. In recent years, there has been significant controversy about nano-foods and debate has led to social scientific inquiry of many factors that seek to explain and predict public attitudes and purchase intentions regarding nano-foods. Such studies have investigated the roles of demographics and sociographics, value predispositions toward science and technology, preferences for natural products, trust in regulatory agencies, science knowledge, and media attention. This large-scale survey-based study granularly assesses the role of each of these factors and improves the predictive models by further evaluating concepts from Protection Motivation Theory in OLS regression models. Findings demonstrate that the incorporation of threat- and coping-appraisals provide the most predictive and explanative models to date with regards to attitudes and purchase intentions of nano-food products.

P.19

NANoREG Framework and Toolbox for the safety assessment of nanomaterials

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The European Commission, the European Chemicals Agency (ECHA), the Organisation for Economic Co-operation and Development (OECD) and the scientific community have worked closely together in recent years to improve the knowledge on environmental health and safety (EHS) aspects of nanomaterials (NMs), remove hurdles and concretely help stakeholders in addressing regulatory requirements for NMs. Several nano-specific issues are still difficult to address efficiently and may hamper the safety assessment of NMs. The NANoREG project, funded by the European Union's 7th Framework Programme and entitled "A common European approach to the regulatory testing of nanomaterials", has analysed means of overcoming these obstacles in the "Framework for safety assessment of NMs". The scope defined for the Framework is two-fold: firstly, it analyses the applicability of the current European regulatory framework to NMs, with focus on the European REACH Regulation 1907/2006; and secondly, partners also discuss Safe-by-Design (SbD), Nanospecific Prioritisation and Risk Assessment (NanoRA) and Life Cycle Assessment (LCA) as valuable paths to a more efficient medium-to-long-term achievement of REACH objectives for NMs. While developing the Framework, a coordinated effort was made to harmonise the use of specific wording within the project ("NANoREG harmonised terminology"). The Framework serves as an overarching structure that indicates where and how to apply the tools collected in the "Toolbox for safety assessment of NMs". The Toolbox focuses on 'working tools', i.e. tools that are ready to use by industry and authorities, and also differentiates between tools that are already accepted at regulatory level and those that are products of research initiatives with no particular status of acceptance. Both the Framework and the Toolbox have been developed via a collective effort of project partners under JRC's leadership and are supported by a NANoREG-wide consensus.

P.20

Operationalising responsible innovation in the nanomedicine sector

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Responsible Innovation (RI) has become a popular concept in the European Commission's programs for anticipating potential implications, ethical dilemmas and as way governing new and emerging technologies. However, few empirical studies exist exploring the perceptions on RI of experts involved in research and development of novel technologies and products, and fewer still exist investigating nanotechnology enabled medical applications which are believed will transform healthcare in near future. In contrast, a significant body of literature has built up since the adoption of the RI concept by the EC, debating the tenet of the concept and its strengths and weaknesses. However, operationalisation frameworks for RI are lacking preventing its uptake. In order to fill these gaps, 66 experts, from the nanomedicine innovation pathway, were interviewed regarding their understanding of RI. The interview data was analysed both by inductive and deductive approaches, and was used to develop a framework by which RI can be made operable in everyday lives of innovators and regulators. The experts understood innovation in the medical sector to be inherently RI because of its contribution to improvement of human health; however, to the question on who should be responsible, responses were varied. Responsibility was attributed to manufacturers, scientists, innovators, regulators, etc. and shared and collective responsibility was discussed. Analysis of the interview transcripts further revealed that RI can be framed around current discourses on risk, environmental sustainability, corporate social responsibility, health and safety and stakeholder engagement. The proposed RI operationalisation framework discussed here is not entirely new - it is based on the dimensions of RI proposed by Owen et al. (2013) and uses existing, more mature concepts of sustainability, public engagement, and associated frameworks, guidelines, codes and practices, to facilitate its implementation.

P.21

Perspectives of experts on environmental risks and risk assessment of nanomedicines

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It is believed that in the next couple of decades nanotechnology enabled health care applications will have significant influence on diagnosis, prevention and treatment of disease. Nanomaterials offer numerous advantages due to the unique chemical and physical properties of materials at nanosizes, facilitating rapid and precise detection of biomarkers, targeted delivery of drug payload etc. Pharmaceutical products (PPs) have been detected in various environmental compartments and low level chronic exposure to PPs has induced adverse and sometimes unexpected effects on non-target organisms, raising the question of potential environmental risks from increased usage of nanomedical products. Novel toxicities could arise from different modes of action (compared to (macro) molecular drugs). The risks to human health from nanomedicines are being addressed by appropriate regulatory agencies; however, risks to the environment are sparingly discussed. To fill this gap, perceptions of eminent experts from the nanomedicine innovation chain regarding possible hazards and risks from nanomedicine, and the adequacy of current environmental risk assessment framework were explored. 62 interviews with experts were conducted using a pre-set questionnaire shared with them, and a general inductive approach was used to analyse the data. Interviewees mentioned that hazards were possible but risks were unlikely from nanomedicines. However, they qualified their statements by comparing risks from nanomedicine with risks from nanomaterials in other industries, conventional pollutants in the environment and larger global issues like climate change. Regarding adequacy and adaptation of current environment risk assessment frameworks for use with nanomedicines, expert perceptions were more varied; some argued complete overhaul of the risk assessment framework including change in toxicity endpoints whereas others suggested that the framework was adequate, albeit some customisation was needed.

P.22

Development of a Real-Time Information and Monitorning System to Support the Risk Assessment of Nanomaterials Under REACH

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Within the LIFE NanoMONITOR project, an innovative systems to monitor the concentration of ENMs in indoor workplaces and the environment is being developed. This system is based on an on-line data analysis tool for collecting and archiving data on environmental concentrations of Engineered Nanomaterials (ENMs), coupled with a newly developed prototype and low cost nano-pollution monitoring systems able to continuously measure key airborne nano-pollutants.

A first prototype has been developed, being based on the implementation on a single instrument of a nanoparticle measurement unit able to count particles below 700 nm, an air sampling unit including cascade impactors and filtering units, and a data management software to support the acquisition of data on the concentration of ENMs in real time.

The measurement unit follows the diffusion charging principle, where the airborne particles in the nanometer range captured by the device are electrically charged by corona discharge from a needle-tip electrode set at a voltage high enough to locally ionize the air. The charged particles are subsequently captured on a filter placed inside and electrically isolated in a Faraday cage, where a current meter measures the total current from the charged particles considering that the total current depends on the particle number concentration and the particle size.
The software application developed is designed to support the capture of monitoring data from sensors in real-time, real-time QA/QC for data imports, data storage including automatic incremental backup strategies, graphical display, as well as a range of analytical tools for exposure and risk analysis.

NOTES