World Congress on Risk 2012: Risk and Development in a Changing World

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Session Schedule & Abstracts

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Common abbreviations

T3-B
Emerging Risks in Synthetic Biology: Part 2

Room: Bayside 204 B 1:30-3:00 PM

Chair(s): Alison Cullen

T3-B.1 Risk analysis in synthetic biology: global and emerging. *Schmidt M, BIOFACTION, Dep. for Technology Assessment* schmidt@biofaction.com

Abstract: Synthetic biology (SB) is an interdisciplinary science and engineering field built on genetic engineering, synthetic chemistry, information technology and electronic engineering. SB is the design and construction of new biological functions and systems not found in nature. Acknowledging the potential benefits of SB for the knowledge based bio-economy, the European Group on Ethics in Science and Technology in 2009, and the US Presidential Commission for the Study of Bioethical Issues in 2010, published recommendations that both contained a request to investigate novel biosafety and risk analysis issues in SB. Based on previous analysis and ongoing work in risk analysis of SB, this presentation will discuss why SB needs new methods of risk assessment. In particular, the following cases warrant an adaptation of current practices: DNA-based bio-circuits consisting of a larger number of modular bioparts; the survivability and evolvability of novel minimal organisms—used as platform/chassis for DNA based biocircuits—in different environments; and exotic xenobiological systems based on an alternative biochemical structure, e.g. genetic material based on novel types of nucleotides. An important task for risk analysis is to explore how SB itself may contribute towards overcoming existing and possible future biosafety problems by contributing to the design of safer biosystems. These systems, meant to mitigate the risks without limiting the potential benefits, entail e.g. the design of less competitive organisms changing their metabolic pathways; replacement of metabolic pathways that have an in-built dependency on artificial biochemicals (auxotrophy); construction of xenobiological systems based on an alternative biochemical structure to avoid horizontal gene flow to and from wild species (genetic firewall); or the synthesis of protocells that lack key features of living entities, such as growth or replication.

T3-B.2 Regulatory decision-making frameworks for consumer products. *Healy M, National Industrial Chemicals Notification and Assessment Scheme (NICNAS)* marion.healy@nicnas.gov.au

Abstract: Regulation of consumer products for hazardous chemicals or genetic modifications is crucial for environmental health risk assessment and analysis. These hazards include industrial pollutants and other environmental contaminants along with emerging technologies such as nanotechnology that can ultimately impact food supplies, water and cosmetic products, among others. Different classes of products require specific regulatory frameworks for assessing human health risk. Within the framework for a product class, there is a need for harmonization of the risk assessment and chemical safety process. We provide an overview of regulatory decision-making frameworks for selected consumer products in Australia. One of the products addressed will be genetically modified organisms (GMOs). People have been manipulating the genetic make-up of plants and animals for countless generations. This involves selecting plants and animals with the most desirable characteristics (e.g. disease resistance, high yield, good meat quality) for breeding the next generation. Today's techniques of genetic modification provide new ways of identifying particular characteristics and transferring them between living organisms. GMO labeling policy for foods is under intense development, and in the absence of any international consensus, countries are either choosing mandatory labeling or adherence to voluntary labeling. In Australia, it is mandatory for GMO foods to be identified on food labels. Most dealings with GMO organisms must be licensed, and licenses are not to be issued unless any risks they pose can be managed in such a way as to protect the health and safety of people and the environment. There is thus a need to develop and harmonize regulatory frameworks for consumer products (including GMOs, chemicals and other hazards), and to incorporate these frameworks into risk analysis and public health decision-making.

T3-B.3 Metabolic Engineering through Systems and Synthetic Biology. *Vickers C.E., Australian Institute for Bioengineering and Nanotechnology, The University of Queensland* c.vickers@uq.edu.au

Abstract: Metabolic engineering is the rational re-design of cells and organisms for the production of specific industrially-useful compounds. My research focuses on engineering microbes (yeast and E. coli) for production of biological replacements for materials currently produced from petrochemical feedstocks. Production via microbial fermentation is more environmentally friendly, uses renewable feedstocks, and results in higher-purity products (thereby decreasing production costs). We are interested in developing microbes capable of efficiently using sucrose, a major agricultural product in Australia, as a feedstock for industrial bioprocesses. Microbial platforms are being developed for production of a range of biochemicals, including polyhydroxybutyrate (a biodegradeable plastic) and isoprenoids (a group of biochemicals with a wide range of industrial applications, including rubbers and biofuels). The tools of systems and synthetic biology are used to develop these industrial biocatalysts.

T3-B.4 Risk assessment of new technologies: Bridging the regulatory divide between high and low income countries. *Roca M, Zamorano University, Honduras; Keese P, Office of the Gene Technology Regulator, Australia* mmroca@zamorano.edu

Abstract: Do expensive risk assessments result in better decisions? Risk assessment of genetically modified organisms (GMOs) is used as the foundation of sound regulatory decision making in most countries. This includes both high income countries such as Australia and low income countries such as small developing countries in Central America. However, there exists considerable disparity in the regulatory capacity to evaluate risks from this rapidly advancing technology. Regulation of GMOs in Australia involves a dedicated agency with about 50 staff, of which more than dozen have PhDs. Risk analysis training is integral to the agency's operations. In small developing countries, GMO regulation relies on a few government staff largely unfamiliar with risk analysis and the unpaid services volunteered by a few national researchers struggling to sustain their own activities. GM plants approved for commercial release in Australia are intended to reduce crop production costs. In Honduras, the only country in Central America that has approved commercial GM crops, GMOs offer the potential to manage important crop pests and improve weed management practices (often done by women and children as unpaid labour) or the potential to slow the spread of rampant diseases such dengue fever (exacerbated by climate change), improve the nutritional value of staple food crops, and increase production to address chronic, widespread poverty. However, regulation has a high cost, especially when complying with international requirements that assume regulatory approaches in high income countries are necessary and appropriate for all. Consequently, capacity building activities may fail to provide enduring solutions. Additional approaches are required to allow local knowledge and skills to satisfy local and regional needs for sustainable development. These include online access to external knowledge and resources, adoption of regulatory decisions in other countries, use of checklists and other simple risk assessment tools, as well as regional sharing and outsourcing of risk assessments.

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