New Approach Methods to Assess Chemical Risks in Food and Other Supply Chains

Steven Maguire (University of Sydney)

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Theme: #2, Managing risks in a connected world [Sustainable Agriculture & Food Systems]
Host collaborator: Professor Niladri Basu
Host institution: McGill University, Montreal, Canada
Dates of fellowship: 16 weeks during the period 24 May – 26 October 2023

I consent to this report being posted on the Co-operative Research Programme's website.

1. What were the objectives of the research project? Why is the research project important?

The goal of my sabbatical visit to the Faculty of Agricultural and Environmental Sciences at McGill University (Montreal, Canada) was to collaborate with Professor Basu on developing and getting implemented new methods to characterize the risks associated with the presence of chemicals in supply chains, including those for food (i.e., from farm to fork), and in the environment when contaminants arise as by-products of these supply chains. The objective was to continue to leverage "Engaged Innovation Research" to develop, test, validate, and implement new approach methodologies (NAMs) for regulatory toxicity testing, to predict better the toxicological and ecotoxicological profiles of new and existing substances (including in their nanoforms), to design hazardous chemicals out of supply chains, including those for food, over time.

The Government of Canada defines NAMs as: "any technology, methodology, approach or combination thereof that can be used to replace, reduce or refine (known as the 3Rs) animal toxicity testing and allow for more rapid or effective prioritization and/or assessment of chemicals", (e.g., in vitro testing). For new substances, NAMs can be used early in corporate R&D laboratories to prevent over-investment in chemicals with low likelihood of regulatory approval; while for existing substances, NAMs can be used by regulators to identify emerging contaminants before exposure concentrations increase beyond those associated with acceptable levels of risk. This work is important and timely because current regulatory practices are challenged to keep pace with obligations for toxicity testing due to reliance on historical methods that require extensive animal tests which are prohibitively time-consuming, expensive, and ethically questionable.

The visit aimed to deepen and extend an existing multidisciplinary collaboration in which social scientists (including myself), ecotoxicologists, biologists and bioinformaticians developed, tested, validated, and commercialized quantitative polymerase chain reaction (PCR) arrays (EcoToxChips) and a data evaluation tool (EcoToxXplorer.ca) for the characterization, prioritization, and management of environmental chemicals and complex mixtures of regulatory concern.

2. Were the objectives of the fellowship achieved?

Yes, the objectives were achieved. The collaboration with Professor Basu was deepened and extended in the following ways: (1) work launched during the EcoToxChip project was further advanced in a series of papers targeted at peer-review journals; (2) the social science research activities of a follow-up project were planned in more detail in meetings with regulatory partners at Environment and Climate Change Canada (ECCC); and (3) a broader, more ambitious research project on NAMs was scoped, with an extended team of scientists and regulatory, industry and civil society partners, for a pending 2024 funding application. At the core of these three projects, each at a different stage of its life cycle, is "Engaged Innovation Research", which represents a novel approach to science commercialisation. The CRP Fellowship funding allowed us to elaborate and further develop this methodology.

Engaged Innovation Research refers to the systematic production of new knowledge about innovation by social science researchers who are embedded alongside natural science, engineering, and/or biomedical researchers as full members of multidisciplinary inventing teams. Because innovation challenges do not respect disciplinary boundaries and cannot be adequately tackled with knowledge

from just one part of the University, the integration of social scientists into inventing teams can be invaluable in helping to overcome these challenges in a timely manner. While studying innovation "in the making" using ethnographic methods to produce and publish *new* knowledge about it, embedded researchers simultaneously contribute to innovation by mobilising *existing* knowledge in a timely manner to position the team advantageously and advance its innovation journey. The presence and contributions of embedded social scientists help inventing teams to become both (a) more business minded and customer-focused so their innovations are more easily de-risked and made commercialisation-ready; and (b) more societally minded and stakeholder-focused if their innovations may pose novel risks.

3. What were the major achievements of the fellowship? (up to three)

1) (Re)Drafting and development of papers launched as part of the EcoToxChip project, addressing the following topics: navigation of tensions associated with the validation of new regulatory science tools; institutional constraints and affordances on design thinking processes and outcomes; and the Engaged Innovation Research methodology.
2) Meetings with regulatory partners to plan the work of a social scientist post-doctoral fellow who will be embedded with the regulators beginning in 2024 as they seek to determine if the EcoToxChip Test System may be validated and standardized for their use in chemical risk assessment workflows, carrying out a series of regulator-academic case studies.
3) A series of meetings with new academic and regulatory partners to scope a major funding application to be submitted in 2024, including the organization and execution of a "Design Thinking" workshop that brought together >25 participants from academia, government, industry, and civil society to identify the most pressing needs for NAMs – importantly, from users' perspectives – in human health and environmental chemical risk assessment.

4. Will there be any follow-up work?

Yes, there will certainly be follow-up work from our deepened and extended collaboration.

1) We aim to submit papers described above to international conferences, e.g. ones organized by the Society for Environmental Toxicology and Chemistry (SETAC), in 2024, following which they will be finalized for submission to peer-reviewed journals.
2) It is planned that a social scientist post-doctoral researcher will become embedded in the day-to-day activities of regulators at ECCC as of mid-2024, to carry out Engaged Innovation Research with regulators as they seek to determine if and how they may be able to adopt and integrate the EcoToxChip 'Test System' into their risk assessment workflows.
3) The newly scoped funding application described above will be submitted to a Canadian funding program early in 2024.

5. How might the results of your research project be important for helping develop regional, national or international agro-food, fisheries or forestry policies and, or practices, or be beneficial for society?

The Engaged Innovation Research described above is being undertaken to generate a series of economic, human health and environmental benefits that will be realized with the widespread implementation of NAMs in chemical management practices globally. Current regulatory practices are challenged to keep pace with obligations for toxicity testing because of reliance on historical methods that require extensive animal tests, which are prohibitively time-consuming, expensive, and ethically questionable. For example, a full human health risk assessment for just one pesticide costs > $20 million and takes > 4 years. Further, conventional tests that quantify death and disease in vertebrate animals also do not provide information on the molecular mechanisms leading to toxic effects, which is critical to understanding impacts and relevance across diverse populations and

species. As a result, the central role of these tests in risk assessment is now widely challenged; and numerous governments worldwide have committed to phasing out animal testing.

NAMs promise to increase the effectiveness of toxicity testing and risk assessment, rendering it more protective, efficient, affordable, and ethical. But these benefits are only realised if, and when, NAMs are widely implemented, hence the importance of mobilizing social scientists alongside natural ones to accelerate the organizational and institutional change that is required in regulatory science settings.

6. How was this research relevant to the objectives of (a) the CRP?; and (b) the CRP research theme?

The main aim of the *OECD Co-operative Research Programme ("CRP")* is (from website): "*to strengthen scientific knowledge and provide relevant scientific information and advice that will inform future policy decisions related to the sustainable use of natural resources, in the areas of food, agriculture, forests and fisheries".* Specifically, Theme 2 focuses on "*strengthening resilience in the face of multiple risks in a connected world through research helps to anticipate, pre-empt and cope with potential and real impacts on agricultural systems and food security."*

The research undertaken is directly relevant to the CRP's main aim and the objective of Theme 2 insomuch as the research focuses squarely on the science-policy interface and risk. The research centres on deepening academic-regulatory collaboration to speed the translation of leading-edge science into viable, policy-relevant tools for toxicity testing, making risk assessment more protective, efficient, affordable, and ethical. Many of the case studies by my McGill partners have focused on chemicals in agricultural systems including common dietary nanoparticles used in the food industry (e.g., Ag, SiO_2, TiO_2) and pesticides of regulatory concern by Fisheries and Oceans Canada.

7. Satisfaction

The CRP Fellowship fully met my expectations. It facilitated a productive overseas visit to deepen and extend my collaboration with Professor Basu, where I was also presented with career opportunities, which I gratefully seized, to expand my network of collaborators to a broader set of scientists and regulatory partners.

This research visit represented the solution to a notable practical problem: the original OECD CRP Fellowship was awarded in late 2020 to Professor Basu to visit the University of Sydney during his sabbatical year to deepen and extend our collaboration – a trip that had to be aborted due to enduring COVID-19 travel restrictions. As a Plan B, Professor Basu proposed that I travel to McGill University during my sabbatical year to continue our collaborative research. The proposal was accepted by the OECD CRP staff and the visit completed, hence this report. On behalf of Professor Basu and myself, I thank the OECD CRP team for their understanding and flexibility in a difficult situation.

8. Advertising the Co-operative Research Programme

I learnt about the CRP from Professor Basu, a natural scientist collaborator. To make the CRP more visible, I suggest more systematically bringing it to the attention of social scientists working in Business Schools because their expertise in innovation, organizational change and institutional transformation is directly relevant to the science-policy interface and the societal transitions required to achieve sustainable development.