Environmental Fate and Risks of Nano-enabled Pesticides

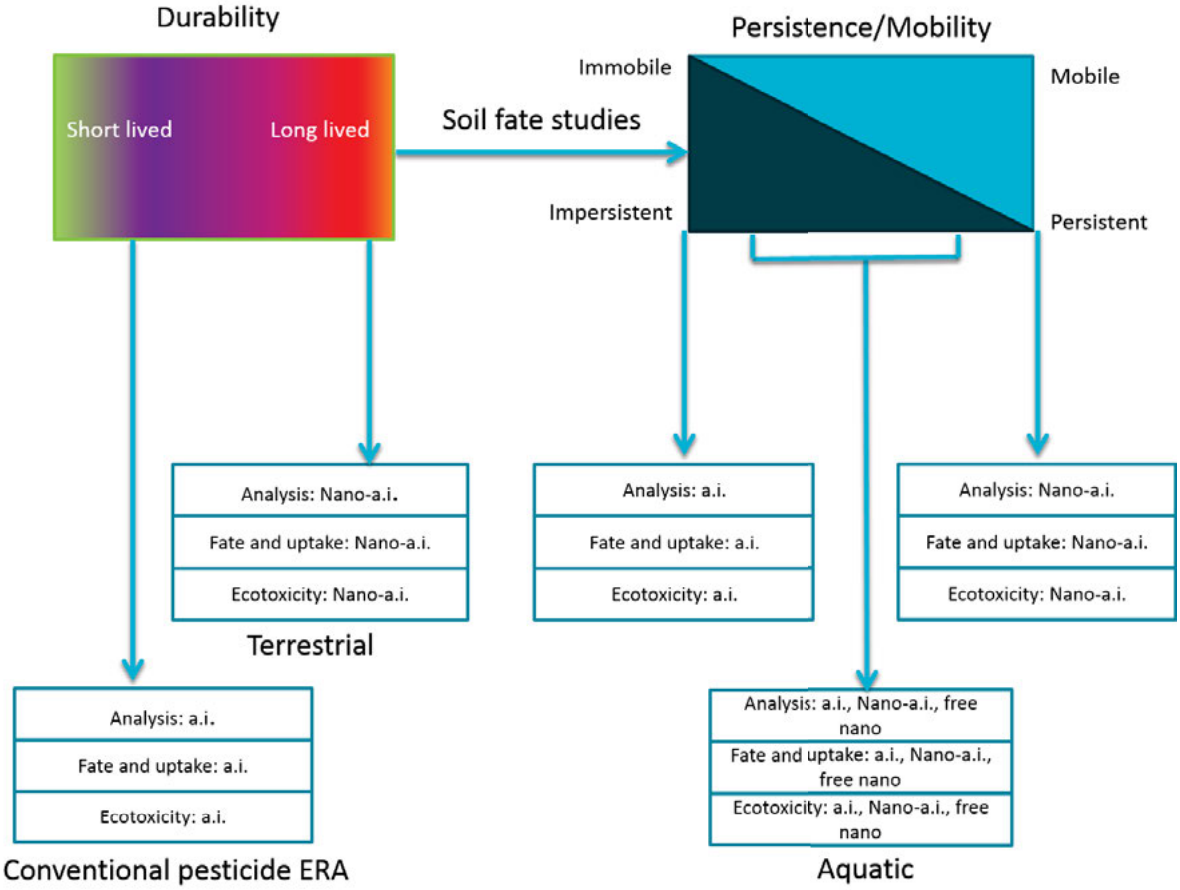
Nanotechnology is emerging as a highly attractive tool for the formulation and delivery of pesticide active ingredients, as well as enhancing and offering more effective and environmentally friendlier crop protection products. A number of formulation types have been suggested, including emulsions (*e.g.* nanoemulsions), nanocapsules (*e.g.* with polymers), and products containing pristine engineered nanoparticles (such as metals, metal oxides and nanoclays). Some nano-enabled pesticides are in the pipeline and are expected to be presented for registration to the regulatory agencies. For example, US EPA recently registered a nano-enabled pesticide, AZteroid, which is based on Vive Crop Protection's Allosperse (a polymer-based delivery system).

The increasing interest in the nano-enabled pesticides raises questions as to how to assess the environmental risk of these products for regulatory purposes. Therefore, there is a need to develop a set of guiding principles to facilitate a harmonized approach for the environmental risk assessment (ERA) of nano-pesticides.

In response to the above, we have just concluded an IUPAC project on "Guiding principles to facilitate a harmonized ecological risk assessment framework for nano-pesticides in the environment" (www.iupac.org/project/2012-020-3-600). The project has laid down some guiding principles and suggested an approach for consideration by regulatory agencies and industry (Kookana *et al.* 2014).

The project found that the existing tiered risk assessment approach, such as that used in the European Union, remains a useful framework for the risk assessment of nano-pesticides. In many situations, existing approaches can be used with some modifications and adaptations to cover nano-pesticides. In this regard, a crucial decision making step relates to the durability of a nano-enabled pesticide product and the fate of the product in soil (Figure 1). This criteria allows an assessment of whether a new nano-enabled product could be treated as a conventional pesticide, or if it needs to be treated differently, as a product that demonstrates

Figure 1. Conceptual framework for assessing the environmental risk assessment (ERA) of nanopesticides (taken from Kookana et al. 2014, with permission from ACS)



Project participants in a workshop in York (UK) in May 2013, with Rai Kookana (far right).

an altered efficacy or fate or toxicity profile. For example, a nano-formulation that is short-lived, *i.e.,* it releases the active ingredient (a.i.) relatively rapidly, the product can be treated as a conventional product. For relatively durable formulations, potential alterations in fate and behavior resulting from the nanoformulation can be accounted for, with some adaptions to existing approaches (Kookana *et al.*, 2014).

The industry feedback received so far indicates that the above appears to be a workable approach. The framework proposed by Kookana *et al.* 2014 is now being considered by regulatory agencies internationally (*e.g.* USEPA, Environment Canada, APVMA Australia).

Stakeholder consultations undertaken during the above project, especially with industry representatives and regulators, highlighted the need for some specific guidance on data requirements and the associated methodology, based on specific product-types and driven by the problem-formulation stage of risk assessment. Practical information is needed to answer the following key questions:

1. When a new product is presented to the regulators, what are the key questions that they would like to ask? This essentially defines the **problem formulation step** in the ERA framework.
2. What are the key characterizations and analytical requirements for the specific product that may be necessary to answer the question posed at 1 for a specific product type?
3. What are the specific methods or approaches for environmental fate and effects that are readily available and appropriate to answer the questions for the specific product under consideration?
4. What are the current knowledge gaps and uncertainties that the regulators and industry need to consider for a pragmatic approach to decision making?

It was recognized that there is a need to enhance understanding among industry and regulators on:

- The environmental fate and effects data that regulators will require to determine the risk profile of nano-pesticides.
- What methods/approaches are appropriate and acceptable to give industry confidence in obtaining and submitting the data required to satisfy the regulatory requirements?

Therefore a sequel project has been initiated to develop a practicable approach for generating sound data required for satisfying ecological risk requirements for the purposes of registration of nano-enabled pesticides.

Reference

Kookana et al. 2014, *Journal of Agriculture and Food Chemistry*, **62**:4227-4240; http://dx.doi.org/10.1021/jf500232f)

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www.iupac.org/project/2016-016-2-600