

Submission re. APVMA paper on nanomaterials and regulation of agricultural products



Overview

The APVMA paper, *Regulatory Considerations for Nanopesticides and Veterinary Nanomedicines* (hereafter *The Paper*) is a useful and generally thorough overview of current research into the broad variety of environmental, health and safety issues relating to nanomaterials. The Paper, however, makes the implicit assumption throughout that the benefits associated with the use of nanomaterials in pesticides and veterinary medicine outweigh the risks. The Paper tends to downplay the risks associated with the use of nanomaterials (usually by way of criticising relevant studies) and uncritically supports the claimed benefits.

While extolling the potential virtues of nanotechnology in agriculture, there is no critique of the industrial model of agriculture and the ways in which the use of nanomaterials will simply perpetuate models of production that are resource, energy and chemically intensive. There is extensive literature that calls into question the kind of ‘treadmill’ approach to chemical agricultural inputs that the use of nanotechnology supports. This kind of critique matters, because many of the ‘problems’ that nanotechnology is promoted as able to solve are problems that have been created by the current industrial and input intensive agricultural system.

Regulatory adequacy

The Paper claims there is ‘general consensus’ that the current regulatory framework is adequate for the moment. It is not clear where this consensus exists but in the absence of applications, assessments and surveillance, it’s a meaningless thing to say. In fact, it is not clear how the current regulatory framework actually applies to nanomaterials nor is it clear that businesses seeking to use nanomaterials in agricultural products even need to apply to the APVMA for authorisation for such use.

The Paper claims that those seeking to use nanomaterials in agricultural products must apply for authorisation. While there are information requirements relating to nanomaterials in the application, there does not appear to be any requirement that nano forms of existing chemicals are subject to any application requirement. The APVMA website previously claimed that “data supporting a chemical or chemical product that contains engineered nanomaterials will be independently evaluated, regardless of a conventional counterpart product being approved.” Although they noted that “not all engineered or manufactured nanoscale materials are novel and will need to be assessed.”¹ However, this ostensible requirement has now been removed from the APVMA website and replaced with the statement that “the APVMA has not yet published any detailed guidelines specifically about the registration and regulation of products containing nanomaterials.” It is suggested that those proposing to register a product using nanomaterials ‘should’ first contact APVMA, but this is not mandatory.²

In the absence of any nano-specific regulations, the current regulations will only capture nanomaterials if they are new chemicals that would be subject to regulatory controls regardless of particle size. Reformulations of existing chemicals at a nano scale, nano-emulsions, nano-

encapsulations and nanomaterials that are not active ingredients are not currently subject to any regulatory requirements.

This is also true of the labelling 'requirements' noted in The Paper. The new requirement regarding Relevant Label Particulars could – and should - include a requirement that nanoscale forms of chemicals or formulations be listed on product labels. While the APVMA paper says nano particulates should be “appropriately labelled” it is not mandatory ('should' not 'shall') and it isn't clear what 'appropriately' means.

Finally, we strongly agree with the National Toxics Network view that the existing regulatory regime has failed to safely or properly assess agricultural chemicals. If the current regulatory regime has failed then clearly it cannot be depended upon to address nanotechnology. Of particular concern is the alignment with industry, exhibited through both the 'approvals' process and the slowness with which APVMA responds to substantial evidence that certain chemicals should be reviewed or removed from the market.

Regulatory future

The paper accepts that change in regulations may be required in the future but lacks any clear vision of what regulatory changes may be needed and what shape and scope they may have.

In some ways, it appears that the APVMA is going backwards. In a 2012 review of agency responses to the 2007 Monash review of regulatory gaps,³ APVMA was complimented for filling some of the identified gaps. For example, the APVMA website indicated that chemicals reformulated at the nanoscale would be treated as new substances. However this has not happened and is no longer mentioned on the APVMA website.

The Monash review also noted that all chemical registrations were going to be reviewed and that this process would capture nanomaterials in agricultural chemicals . However, the review of chemicals was abandoned by the current Government.

Applications for new registrations include information requirements relating to nanomaterials, but as the APVMA has noted, these are for information only. The APVMA does not require companies to submit new applications for reformulated agricultural chemicals that contain nanomaterials.⁴

The Precautionary Principle

In a variety of ways, the current regulatory regime has abandoned the precautionary principle – under virtually any definition. The lack of precaution in relation to nanomaterials is apparent in The Paper a number of ways.

Uncertainty

Although The Paper acknowledges the many gaps in our knowledge of nanomaterials and their behaviour and fate in the agricultural environment, it doesn't address uncertainty well. Uncertainty regarding the behaviour, impacts, life-cycle, interactions, synergies and long term fate of nanomaterials are all recognised in The Paper, but nothing is proposed for dealing with this uncertainty. There is no recommendation that research priorities be established and funded in order

to reduce uncertainty, as the National Research Council has done in the US.⁵ There is no suggestion that the regulatory regime must become more cautious with such high levels of uncertainty. Instead, uncertainty is simply accepted as the current state of play.

Ignorance

In the realm of nanotechnology there are many significant gaps in our knowledge and shared understanding that have an important impact on the level of risk and the need for precaution. The lack of standardised testing methodologies; the lack of agreed reference materials; the lack of a register of nanomaterials allowing these materials to be tracked; and the lack of a regulatory definition are all forms of ignorance that should profoundly affect regulatory approaches. If, for example testing methods to detect nanoemulsions *in situ* don't exist, it would seem clear that any precautionary approach would not permit release until such tests are developed and validated so that the environmental fate of nanomaterials can be ascertained.

Instead, ignorance like uncertainty is ignored. How can the existing regulatory system be adequate when the tools necessary to conduct a basic risk assessment for nanomaterials are still lacking? Any analysis of the adequacy of a regulatory system must include an evaluation of the adequacy of the tools that are required for assessment, monitoring and regulation of nanomaterials. As the US National Research Council has pointed out we still lack a host of basic tools critical to risk assessment, detection and enforcement. These include lack of consistent and agreed reference materials; lack of data to calibrate and validate models; and lack of consistent and agreed testing protocols.⁶

Lack of a proactive regulatory approach

It does not appear that the APVMA has taken any active steps to determine whether nanomaterials are already in the agricultural sector, while FoE's research shows they are. The APVMA claims that there are no nanomaterials being used in agriculture because there have been no applications for approval. This barely qualifies as evidence. In light of the lack of nano-specific regulation and the lack of accepted standards and definitions, the industry's failure to apply for approval of nano-products is perfectly defensible from a legal perspective.

The claim that there are no nanomaterials currently in use in Australian agriculture can also be disputed by examining the French register of nanomaterials, which records 64 different nanomaterials used in agriculture and fisheries in France. It is therefore highly likely that nanomaterials are already being used in agricultural chemicals in Australia. Given the knowledge gaps regarding the use of nanomaterials in agriculture - and the recognised problems with methodologies for detecting nanomaterials in soils, plants and foods – legally defensible risk assessments for the use of nanomaterials in agricultural chemicals cannot currently be conducted.⁷ These issues should be resolved before commercial release is permitted.

Shifting the onus of proof

If the safety of a nanomaterial cannot be ascertained then it should have no market. Safety first is a basic tenet of precaution and yet The Paper implicitly shifts the onus onto the public to demonstrate that nanomaterials in agricultural products aren't safe. This shift, again, effectively abandons precaution.

The APVMA implicitly shifts from a safety first to a market first approach by conflating the notion that no evidence of harm is the same as evidence of safety. This kind of regulatory sleight of hand has serious implications. It means that intervention will only occur once 'sufficient' evidence is provided to justify intervention. This occurs rarely. Even when chemicals are banned under other regulatory systems of other countries, the APVMA allows use to continue while the chemical is reviewed. Many of these reviews have continued for over a decade.⁸ As the National Toxics Network has noted, many existing chemicals in use in Australia have been grandfathered in without assessment or adequate data.⁹ These are not regularly reviewed and the legislated review and re-registration of agvet chemicals has now been rescinded.¹⁰ In order to ensure a 'safety first' approach to the use of nanomaterials in agricultural chemicals, there must be explicit requirements that nanomaterials proposed for use in agricultural products must be demonstrated as safe – not simply that, based on company data, they exhibit no evidence of harm.

Definitional issues

The requirement for intentionality in the draft definition of nanomaterials is problematic from a legal viewpoint. Instead, the percentage of nanoparticles (FoE would recommend 10%) can serve that purpose, with no required showing of intent.

The APVMA acknowledges that some particles larger than 100nm may have special EHS concerns, but suggests no regulatory approach to ensure those concerns are addressed. One solution would be to include larger particle sizes (up to 300nm) in the definition. This threshold could be lowered to 100nm with sufficient evidence that larger particles have no unusual properties.

Recommendations

1. Mandatory register and labelling

The APVMA needs to be more proactive in establishing the basic mechanisms that are essential for useful regulation. These include a mandatory register and the mandatory labelling of nanomaterials. Until agencies know what nanomaterials are being used and relevant exposure pathways, they will be unable to properly regulate, track, undertake (or require) comprehensive risk assessments. These are basic requirements and are not being met by any regulatory agency.

2. Nano-specific regulation

The APVMA needs to introduce specific regulations that require the safety assessment and registration of agricultural products containing nanomaterials.

3. Safety first

The underlying legislation should be amended to ensure a safety first approach to all applications and assessments.

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- ² Products of nanotechnology, <http://apvma.gov.au/node/97>, accessed 23 September 2014
- ³ Bowman, D. and Ludlow, K. (2012), Assessing the impact of a ‘for government’ review on the nanotechnology regulatory landscape, *Monash University Law Review*, 38(3), pp. 168-212
- ⁴ *Ibid* pp.178-9
- ⁵ NRC (2013) *Research Progress on Environmental, Health, and Safety Aspects of Engineered Nanomaterials*, http://www.nap.edu/catalog.php?record_id=18475 (accessed 27 March 2014)
- ⁶ *ibid*
- ⁷ OECD (2010) Guidance material for the testing of manufactured nanomaterials, p128.
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- ⁸ Australia is lagging behind when it comes to chemical regulation, News.com, August 2010,
<http://www.news.com.au/technology/environment/australia-is-lagging-behind-the-majority-fo-the-developed-world-when-it-comes-to-chemicals/story-e6frflp0-1225903069771> (accessed 19.11.14)
- ⁹ National Toxics Network, 2011, Submission: A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals Discussion Paper (<http://ntn.org.au/wp/wp-content/uploads/2011/03/COAG-sub-pesticides-toxics-network.pdf>)
- ¹⁰ Farmers applaud scrapping of chemical re-registration bill, ABC Rural, July 2014, <http://www.abc.net.au/news/2014-07-14/agvet-chemicals-amendment-bill/5595282> (accessed 19.11.14)