



**Friends of
the Earth
Australia**

Way too little:

OUR GOVERNMENT'S FAILURE TO REGULATE
NANOMATERIALS IN FOOD AND AGRICULTURE

May 2014



Contents

| | |
|--|-----------|
| Executive Summary | 4 |
| Introduction | 6 |
| 1. What is nanotechnology? | 7 |
| 2. Current trends in food and agriculture | 8 |
| 3. The use of nanotechnology in foods and food processing | 10 |
| 4. The use of nanotechnology in food packaging | 12 |
| 5. Nanotechnology in agriculture | 14 |
| 6. On the Horizon? | 16 |
| 7. Nanofoods and nano agrochemicals pose new health risks | 17 |
| 8. Environmental risks | 21 |
| 9. Research needs | 23 |
| 10. Australian Federal Regulatory Framework | 24 |
| 11. Conclusion | 25 |
| APPENDIX 1 | 26 |

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Executive Summary

In the six years since our 2008 report *Out of the Laboratory and onto our Plates: Nanotechnology in Food and Agriculture*, the use of nanotechnology and nanomaterials across the entire food chain continues to increase. There are more products, more processes and an accelerating rate of commercialisation.

Nanomaterials are being used in a diverse range of products including food additives, supplements, packaging, sensors and coatings; sprays, and vitamins for livestock; pesticides and anti-microbial storage facilities.

In recent years there has been a dramatic increase in the number of nano products available and produced in Australia. Australian companies are now producing products such as nano coatings, nano sprays, nano polymers, liquid nano glass and nano capsules.

In Australia, there are virtually no restrictions on the import of nanomaterials or products containing nanomaterials and nano products can be purchased easily from overseas. Everything from dishwashers that release nano-silver to nano baby bottles, cutlery and cutting boards can be imported.

It is essentially impossible to give an accurate count of the number of nano products now available. This

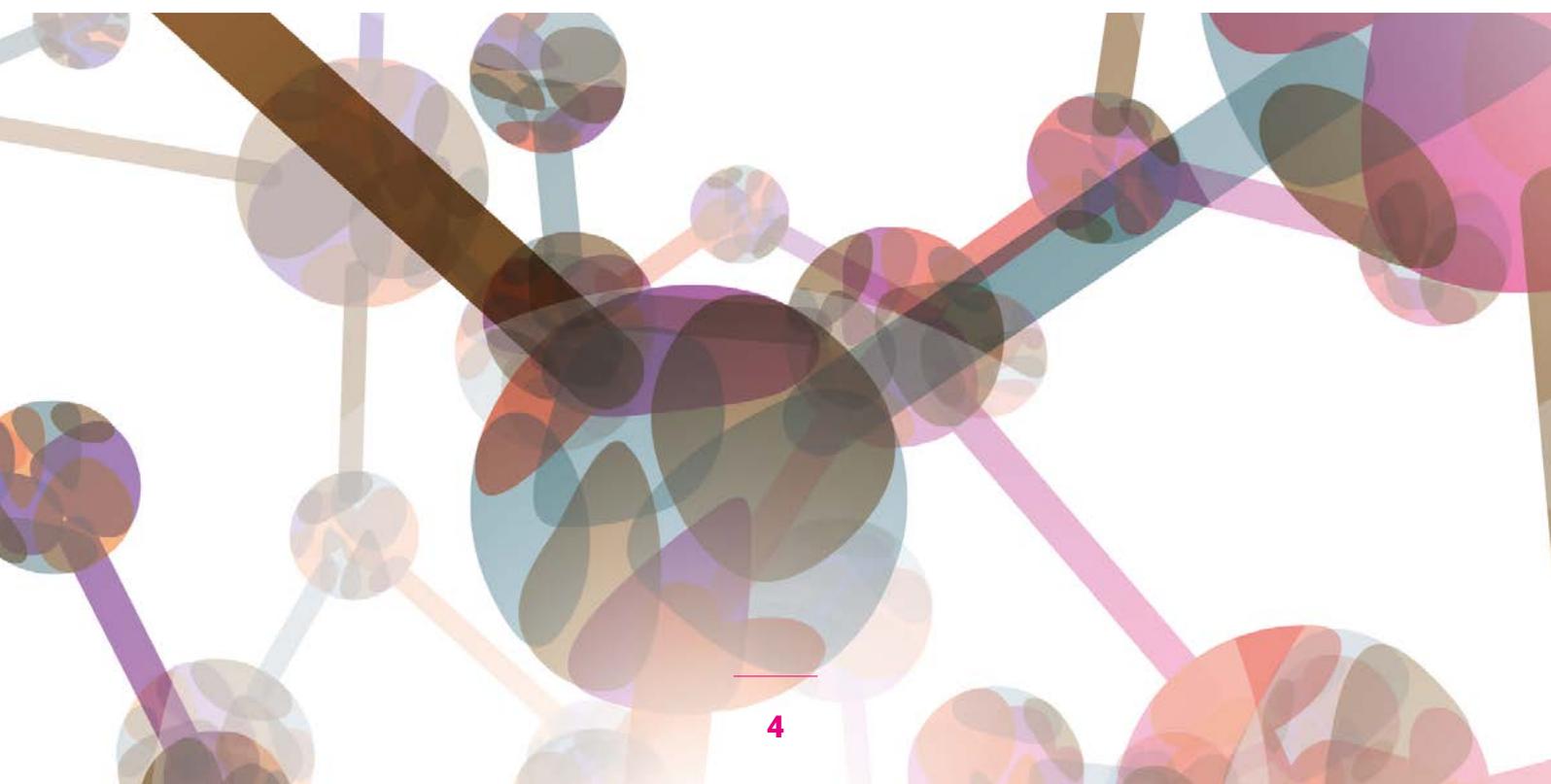
is partially due to the rapid expansion in the number of products since 2008 and partially because there is still no labelling or registration requirement that would allow the public to know what nano products they are consuming.

As this report makes clear, the pace of peer reviewed science examining the environmental, health and safety issues associated with nanotechnology lags far behind the commercialisation. Even basic data, methodologies and reference materials are often lacking, making consistent and reliable risk assessments difficult. There is little understanding of exposure pathways for nanomaterials and little work has been done to assess potential long-term environmental and health impacts.

Even so, since 2008 there has been a growing body of evidence indicating that certain nanomaterials may be harmful.

For example, there is growing evidence that two of the most widely used nanomaterials used in the food sector – nano-silver and nano titanium dioxide – may be harmful to human health.

At the same time, the public has not been kept well engaged or informed, either on the potential environmental, health and safety issues associated



with nanomaterials, or regarding the numerous products that now contain them.

Little seems to have been learned from the ongoing attempts by the biotech sector to shove genetically modified foods down the collective throats of the public. The absence of public support, evidence of safety and regulatory oversight is once again being seen as an opportunity by industry to occupy a market by stealth.

Regulatory intervention remains minimal. Australian regulators still don't even have an agreed nanomaterial definition, making regulation both more unlikely and difficult. Australian regulators maintain a determined hands-off attitude to regulation, preferring instead to keep a watching brief over an industry over which they have less and less control.

This report reveals that the claim by regulators that no food and agricultural products containing nanomaterials are available in Australia is incorrect and that chemical companies are not declaring the nanomaterials they are using. It is clear that our food regulator Food Standards Australia New Zealand (FSANZ) and our agricultural chemicals regulator the Australian Pesticide and Veterinary Medicines Authority

(APVMA) are not exercising the necessary level of diligence.

It is past time for regulators to intervene in this market that currently has so few controls and so many concerns. If we continue with business as usual, Australians will be exposed to even greater and totally unnecessary risks.

While Friends of the Earth Australia (FoEA) makes a number of recommendations in this report in relation to the nanotech industry, there are three basic and critical steps that need to occur immediately:

1. A moratorium on the production and sale of new products containing nanomaterials until necessary research is conducted and regulations to protect human health and the environment are put in place;
2. A mandatory and public register of nanomaterials and products containing nanomaterials in Australia;
3. A labelling requirement for all products containing nanomaterials as recommended by the Federal Government's review of Australia's food labelling laws.¹

Introduction

This report will examine the changes since our 2008 report including the development of new food, food contact and agricultural products. It will review the current literature relating to the potential environmental, health and safety impacts associated with nanotechnology and summarise the Australian regulatory responses to date.

This updated report uncovers the:

- accelerating rate of commercialisation and rapidly increasing number of commercial products containing nanomaterials in the food and agricultural sectors;
- lack of information regarding which nanomaterials have been released and the likely exposure of humans and natural systems to these materials;
- lack of basic steps to allow us to track nanomaterials that have been released, such as labelling and a register of products containing nanomaterials;
- growing gap between the pace of commercialisation and environmental, health and safety assessments;
- increasingly large body of peer reviewed evidence that certain nanomaterials may cause harm to human health or the environment;

- failure of regulators to respond to the growing evidence of risks;
- lack of basic knowledge that is critical in order to fully analyse the particular environmental, health and safety issues associated with nanotechnology.

Six years ago, inaction was based on a perceived lack of data. Inaction is still the norm but that is no longer an excuse our Government can use. Scientists and scientific bodies such as the US National Research Council have given us more than enough evidence to justify a pro-active regulatory regime and a properly funded R&D program that will effectively target those areas of greatest environmental and health concern.

Unfortunately, our Federal Government seems unwilling to provide the levels of funding required for such work or to adopt appropriate regulation. The notion of precaution has been replaced with an attitude that it is the obligation of industry to determine whether their products are safe and regulators will only act when harm is shown. While France, Belgium and Denmark are implementing a mandatory register for nanomaterials and the EU's is in the process of implementing a nano food labelling regime, Australian consumers remain in the dark.

This needs to change.

1. What is nanotechnology?

The term 'nanotechnology' encompasses a range of technologies that operate at the scale of the building blocks of biological and manufactured materials – the 'nanoscale'. While most definitions of nanotechnology relate to a size of between 1-100 nm, there is concern that some particles larger than 100 nm exhibit behaviour similar to nanoparticles, such as very high reactivity, bioactivity and bioavailability.²

Nanomaterials have such diverse properties and behaviours that it is impossible to provide a generic assessment of their health and environmental risks.³ Properties other than size that influence toxicity include chemical composition, shape, surface structure, surface charge, behaviour, extent of particle aggregation (clumping) or disaggregation, and the presence or absence of other chemicals attached to the nanomaterial.⁴ For this reason even nanomaterials of the same chemical composition which have different sizes or shapes can have vastly different toxicity.⁵

In Australia, only one regulator, the National Industrial Chemical Notification Assessment Scheme (NICNAS – our industrial chemicals regulator), has developed a definition of nanotechnology. It is still a 'working' definition⁶:

"...industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale)"

This is not a definition that is necessarily accepted by other Australian regulators. Already there has been a case of a regulator refusing to enforce the law prohibiting misleading conduct in trade because of a lack of a legislatively agreed definition of nanotechnology.⁷

Six years ago, inaction was based on a perceived lack of data. Inaction is still the norm but that is no longer an excuse our Government can use.

2. Current trends in food and agriculture

Nanotechnology has broad existing commercial applications in the food and agriculture sectors, including food processing, supplements and packaging, food contact materials, food monitoring, agricultural chemicals, animal care products and the transport and storage of agricultural goods.

- The lack of any labelling or registration requirement means that information on the presence of nanomaterials in food, food contact materials and agricultural production is limited. It also means there is no reliable estimate of the number of nano products now on the market in the food and agriculture sectors.
- Determining which products contain nanomaterials is further hampered by the behaviour of companies themselves. In some sectors, fear of market rejection means that companies have removed their nano claims, whilst still potentially using nano-ingredients. Meanwhile other sectors such as supplements and agrichemicals actively market products as 'nano' when it is not always clear that they are.

In 2013, the French Government released an initial assessment of nanomaterial use in France, based on data provided by industry for France's mandatory nanotechnology register. This revealed the use of over 500,000 tons of nanomaterials and 3400 different nanomaterial based products in France alone in 2012.⁸

The Woodrow Wilson International Center for Scholars 2013 inventory of nano products lists 200 food and beverage products containing nanomaterials, up from 126 in 2010.⁹

It now appears likely that these estimates are too conservative.

FoEA estimates there are now hundreds of food products and food contact products available and produced in Australia. We base this estimate on the following sources: company claims; foods or food contact products identified in other countries as containing nanomaterials, which are sold here; patents or trademarks held in Australia for the use of nanomaterials in food or food contact materials; the operation in Australia of companies holding Australian patents; and finally the testing of selected products. Appendix 1 details just some of the food and

agricultural products available in Australia that contain nanomaterials and Figure 1 lists some common foods which may contain nanomaterials.

Figure 1: Food product types that may include nanomaterials

- Cream cheese
- Cookies
- Doughnuts
- Coffee creamer
- Chocolate syrup
- Chocolate
- Pudding
- Mayonnaise
- Mints
- Chewing gum
- Popcorn
- Salad dressing
- Oils
- Yoghurt
- Breakfast cereal
- Lollies
- Crackers
- Pasta
- Sports drinks and other beverages

Uncertainty regarding the number and nature of products containing nanomaterials not only highlights the need for reliable information but raises immediate concerns regarding the capacity and interest of regulators in ensuring that human and environmental health are protected.

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The number of products containing nanomaterials will continue to expand rapidly

Both the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) assume that food will increasingly be produced using nanotechnology.¹⁰ Economists estimate that by 2015, 40% of all businesses in the food industry will be working with nanotechnology, with the Asian markets leading, followed by the USA.¹¹

Many of the world's largest food companies, including Heinz, Nestlé, Unilever and Kraft, are exploring nanotechnology for food processing and packaging, as detailed in Figure 2.¹² Many of the world's largest agrochemical and seed companies also have active nanotechnology research and development programs.

Figure 2: A sample of transnational food companies engaged in nanotechnology research and development^{13; 14; 15}

- Altria (Kraft Foods)
- Associated British Foods
- Ajinomoto
- BASA
- Cadbury Schweppes
- Campbell Soup
- Dupon Food Industry Solutions
- General Mills
- Glaxo-SmithKline
- Goodman Fielder
- Group Danone
- John Lust Group Plc
- H.J. Heinz
- Hershey Foods
- La Doria
- Maruha
- McCain Foods
- Mars
- Nestlé
- Northern Food
- Nicherei
- Nippon Suisan Kaisha
- PepsiCo
- Sarah Lee
- Unilever
- United Foods





3. The use of nanotechnology in foods and food processing

Processing aids and food additives

Probably the most commonly used nanoscale processing aids are 'trickle and flow' aids. Nanomaterials such as synthetic amorphous silica (SAS - E551) are added to foods that are in powder form, e.g. salt, vegetable powder, whey powder, egg powder, creamer, instant drink powder (coffee powder), seasoning blends (chilli, garlic powder etc.), powdered sugar and soup powder.¹⁶ SAS is also used as an anticaking agent, thickener and carrier of flavours and consumers are exposed to it on a daily basis.¹⁷ Examples of commercially available nanosilica intended for use in food include Evonik's Aerosil 200F and Aerosil 380F.¹⁸

Titanium dioxide is a common additive in many food products and is used to bleach and brighten confectionery, cheese and sauces. A 2012 study looking at food grade titanium dioxide (E171) calculated that approximately 36% of the particles were nanoparticles.¹⁹ The study found titanium dioxide in a wide range of foods including doughnuts, lollies, chewing gum and chocolate. The titanium dioxide content was as high as 100 mg per serving for powdered doughnuts. Testing undertaken by Friends of the Earth US in 2013 also found nano titanium dioxide on fresh pear, capsicum and apple samples.

Carotenoids of up to 200 nm are used as colourants or antioxidants in drinks or food.²⁰ The Allied Biotech Europe GmbH from Taiwan offers carotenoids as colourants under the name Altratene beta-carotene.²¹ BASF also sells LycoVit – an antioxidant containing nano lycopene.²²

Functional Foods

The food industry has invested heavily in products that they claim will bring consumers nutritional benefits such as yoghurts that are claimed to strengthen the immune system, improve digestion, or lower cholesterol. Dairy products, cereals, bread and drinks are mixed with vitamins and minerals like iron, magnesium or zinc, and enriched with probiotic substances, bioactive peptides, antioxidants and soy. Some of these substances are added to foods as nanoparticles. The world market for functional food in 2005 was approximately US\$73.5 billion.²³ The market is growing at 4% per year, much faster than for 'normal' foods. Between 2003 and 2010, the market for these products has more than doubled.²⁴

Some examples of nano functional foods that are already on the market, include yoghurt and drinks containing nanocolloidal platinum or gold that are marketed as 'anti-aging' foods,²⁵ and a Canola Active Oil

from Israel, which claims to contribute to the reduction of Cholesterol.²⁶

The United Nations' Food and Agriculture Organisation (FAO) notes that nanoselenium is being used in Green Tea with claims of health benefits.²⁷

Supplements containing nanomaterials

A wide range of dietary supplements purportedly containing nanomaterials are on the market - for example BASF produces a range of microcapsulated vitamins that contain the vitamins in nanoparticle form.²⁸ However, it is a difficult market to track. It is often unclear whether a product actually contains nanomaterials or whether the term is merely being used in order to market a product. Manufacturers of dietary supplements, unlike food producers, often view nano content as an advantage rather than a disadvantage.

For example, in Australia, Supplements Direct²⁹ advertises nano peptides, nano creatine, nanobolics, nano tribestanol and nano glutamine, but neither distributor or manufacturer websites make clear whether supplements such as these in fact contain nanomaterials.

Nanoscale capsules

Nanoscale capsules are already being used in the processing and preservation of beverages, meats, cheeses and other foods. They are used to enclose



drugs, vitamins, preserving agents, and enzymes. In 2008, we reported that more and more manufacturers offer omega-3 fatty acids and other compounds in 30-40 nm sized capsules that are 4,000 times smaller than previously used microcapsules.

A number of companies offer nutritional formulas containing vitamins, carotenes or anti-oxidants in nano capsules.^{30, 31}

Edible food coatings

Manipulation of materials at the nanoscale can allow food scientists to create 'edible nanolaminate films' which can be used as barrier layers to prolong shelf life. These films can include lipids or clays as moisture barriers; biopolymers such as carbohydrates as oxygen and carbon dioxide barriers; or nanoparticulates and emulsified nanodroplets, which could contain active ingredients to improve taste, texture or appearance.³² Antibacterial substances can also be directly integrated into the edible coating, for instance for meat packaging.³³

Edible coatings containing engineered nanomaterials are reportedly already being used on fruit and vegetables in markets in the US and Canada in order to extend shelf life. Tests conducted in Central and South American farms and packing stations found a number of fruits with a nano coating, including apples, pears, capsicum, cucumbers and other fruits and vegetables that are delivered to the US and Canada.³⁴



4. The use of nanotechnology in food packaging

One of the earliest commercial applications of nanotechnology within the food sector was in packaging.³⁵ It is believed to be largest part of the nano food sector.³⁶

Nano packaging comprises three primary types: barriers, anti-microbials and sensors. Between 400 and 500 nano-packaging products are estimated to be in commercial use now, while nanotechnology is predicted to be used in the manufacture of 25% of all food packaging within the next decade.^{37,38} Visiongain, a 'business information provider', expected the global nano packaging market to have revenues of 'US\$20 billion in 2013'.³⁹

A key purpose of nano packaging is to deliver longer shelf life by improving the barrier functions of food packaging in order to reduce gas and moisture exchange and UV light exposure.^{40,41; 42; 43; 44}

Nanomaterials such as silver and gold, as well as zinc oxide, titanium dioxide, silica and carbon black can be used in packaging to protect food from UV light.^{45; 46} For example, CSIRO has developed a nano coating for bottles that improves light shielding and thus extends shelf-life.

Barrier effects against gases and moisture are achieved with nanoscale silica, alumina and clay and are suitable

for the production of films for the packaging of meat, sausage, cheese or fruit, and also for microwave products and plastic bottles.⁴⁷

The use of composite nanomaterials such as nanoclay in bottles as barriers to oxygen and carbon dioxide is increasingly common and has been patented in Australia.⁴⁸ These are used in bottles for beer, soft drinks, 100% juices, sports drinks and specialty waters.⁴⁹

Nano antimicrobial packaging and food contact materials

Nano packaging and coatings on food contact materials often incorporate antimicrobial nanomaterials so that the packaging itself acts as an antimicrobial agent. These products commonly use nanoparticles of silver, although some use nano zinc oxide or nano chlorine dioxide.^{50; 51}

In 2011, Israeli scientists developed a 'killer paper' for food, which is capable of destroying bacteria such as E. coli within three hours, using colloidal (nanoscale) silver. It has been promoted as ideal for the packaging of meat.⁵²

A large number of nano-based antimicrobial products are available in Australia (see Appendix 1).



Intelligent packaging with nano sensors

Packaging equipped with nano sensors is designed to track either the internal or external conditions associated with packaged food. These could indicate, for example, changes in temperature or humidity or whether the food has gone bad.

A New Zealand company offers ripeSense packaging which contains sensors that measure the oxygen content inside the package. An indicator on the outside of the packaging changes colour when the product has reached its optimum ripeness. The packaging is already being used on pears, kiwi, melon, mango, avocado and other stone fruits. The label was launched in Australia in 2005 by ripeSense and the Australian company J-Tech.⁵³

An Australian patent application is pending for a 'nano-sniffer' less than 150 nm in size. The nano-sniffer will be used to detect chemicals and can include a radio signal using a carbon nanotube antenna. It is intended for a variety of chemical detection uses – including food packaging. The nano-sniffer, according to the application, is suitable for consumption.⁵⁴

The potential human health impacts of consuming

nanosensors is unknown. The extent to which nanomaterials used in sensors can migrate into food is also unknown.

Biodegradable nano packaging

Bioplastics (plant based plastics) are generally less strong than petroleum-based plastics, which are commonly used for packaging and plastic bags. The development of nanomaterials to enhance these bioplastics is being promoted as a solution to this problem.⁵⁵ However, there is still no reliable assessment of the environmental risks of nanoscale fillers in these plastics and whether they are released into the environment when the bioplastics decompose.

The University of Queensland's Centre for High Performance Polymers is involved in the development of nanopolymers. Research from this group led to the establishment of the Victorian company Plantic Technologies Ltd.⁵⁶ They hold at least two Australian patents for starch nanocomposite materials used in packaging, although their website makes no mention of nanopolymers.^{57; 58; 59}

Plantic customers include Kellogg's, Aldi, Sainsbury's, Cadbury and Freedom Foods.



5. Nanotechnology in agriculture



PHOTO: BRIAN ROBERT MARSHALL VIA WIKIMEDIA COMMONS

Nanotechnology is being used in products across the agricultural supply chain, including in chemicals, feed and supplements for farm animals, machinery and storage facilities.

Agrochemicals

Nanotechnology is introducing a new array of potentially more toxic pesticides, plant growth regulators and chemical fertilisers, further entrenching the current system of industrial and chemically intensive agriculture.

Some of the first nano agrochemicals in development are nano-reformulations of existing pesticides, fungicides, plant, soil and seed treatments.^{60; 61; 62} Agrochemical companies are reducing the particle size of existing chemical emulsions to the nanoscale, or are encapsulating active ingredients in nanocapsules designed to break open in certain conditions, such as in response to sunlight, heat or the alkaline conditions in an insect's stomach.

All the leading producers of agricultural chemicals, including BASF, Monsanto and Syngenta are actively researching nanotechnology for use in agriculture and pesticides with nanoscale ingredients are already on the market.⁶³

In the last ten years, over 3000 patents have been filed for pesticides with nanoscale ingredients.⁶⁴ These are mostly nanoscale versions of existing pesticides.⁶⁵ The Internet platform www.nano-technologien.com claims that "Bayer AG has been producing pesticides in this format size on a large scale".⁶⁶

Nanoencapsulation

Since 2010, the Canadian company Vive has offered nanoscale capsules for use with herbicides. Vive Nano has one patent application filed in Australia for the use of nanoparticles with agricultural chemicals.⁶⁷ They are one of the few chemical companies openly promoting nanoscale pesticides for sale.

A number of new pesticide formulations are sold as 'microencapsulations'. Microencapsulation – like nanoencapsulation – is used as a means to improve product handling and delivery to the target pest. Microencapsulation may enhance herbicide transport through stubble, reduce adsorption, and increase herbicide longevity in soil due to the gradual diffusion and release of active ingredient from the capsule.⁶⁸ The companies patenting and marketing microencapsulations (including most of the big chemical companies) do not provide details on the size of these encapsulations. Products such as Syngenta's Subdue MAXX,⁶⁹ Ospray's Chyella,⁷⁰ PennCap-M,⁷¹ and two pending patents for microencapsulated pesticides from BASF^{72,73} may well be nanoscale.

For example, Syngenta has identified microencapsulation as one of the delivery mechanisms for these chemicals in an Australian 'patent',⁷⁴ claiming that its microcapsules 'usually' have a diameter of from 0.1 to 500 microns.⁷⁵ In other words, this product may be both micro and nano encapsulated.

Nano and micro emulsions

Syngenta's Primo MAXX, a growth regulator, Banner MAXX for fungal attack on lawns and Headway and Subdue MAXX, fungicides for turf, are commonly used and available in Australia. They are characterised as microemulsions, however, scientists at the University of Vienna have determined that they are actually nanoscale emulsions. It appears that the term microemulsion is commonly being used as a term for formulations containing organic nanoparticles.⁷⁶

The International Union of Pure and Applied Chemistry (IUPAC) has defined a microemulsion as being between 1-100 nm.⁷⁷ Based on this definition, it appears that the microemulsions used by a number of companies in agricultural products should be understood as nanomaterials. FoEA has identified a number of agrochemicals sold as microemulsions:

- Syngenta's Banner MAXX;⁷⁸
- Hymal's Maldison;⁷⁹
- Thumper Insecticide;⁸⁰
- Clipless – plant growth regulator;⁸¹

- Apple Lustr 331;⁸²
- Rancona C – cereal seed treatment;⁸³
- Greenor, Junction, Plenum 84160 ME, Bastion T (Dow AgroSciences);⁸⁵

While it isn't clear whether these and other microemulsions are at a nanoscale, it is legitimate to assume they are in the absence of evidence to the contrary. Similarly, it isn't clear whether these emulsions contain pesticide nanoparticles. Nevertheless, they can be legitimately seen as new formulations because the active ingredients in microemulsions are intended to breakdown more slowly, be absorbed faster and provide greater bioavailability and faster delivery of bioactives.^{86,87}

The US EPA now requires registration of all pesticides containing nanoscale ingredients, regardless of whether they are active or inactive,⁸⁸ and the EU requires (EC Regulation 1107/2009) that “the interaction between the active substance, safeners, synergists and coformulants” must be taken into account in evaluation of such products.⁸⁹ The position of the Australian regulator, the Australian Pest and Veterinary Medicines Authority (APVMA) is less clear (see Section 10).

FoEA is concerned that the terms microencapsulation and microemulsion are being wrongly used to describe nanoscale encapsulation and emulsion, allowing companies to avoid regulation. The concern is based on the failure of many companies to declare the size of the capsules or emulsions being used. For example, Dow AgroSciences has a pending patent in Australia for ‘Microcapsule suspensions including high levels of agriculturally active ingredients’. Even the patent specification document doesn't detail capsule or particle sizes.⁹⁰ As a recent review of the topic noted, “companies developing formulations in the nano range may choose not to refer to their new products as nanoformulations

(e.g., the term microemulsions), as ‘nano’ may nowadays also be associated with a large public uncertainty on the fate of nanomaterials and effects on human and environmental health.”⁹¹

Nanofertilisers

Fertilisers advertised as nanoscale are freely available on the market, but notably these are not produced by major chemical companies. Nano fertilisers are promoted as ways to improve nitrogen use efficiency, yields, control release, limit waste and improve quality.^{92,93} Nano fertilisers may contain nano zinc, silica,⁹⁴ iron,⁹⁵ and titanium dioxide.⁹⁶ One Chinese company sells a fertiliser which it claims contains over 200 nano scale ingredients.⁹⁷

Animal feed

Nano sized minerals, vitamins, additives or supplements in animal feed are already on the market. For example, a feed additive has been developed comprising a natural biopolymer from yeast cell walls that can bind mycotoxins to protect animals against mycotoxicosis.⁹⁸ Nano zinc oxide is sold for use as a growth promoter in animal feed.^{99,100,101} Nano liquid vitamin mixes are also available for use in poultry and livestock feed.¹⁰² A Thai company, Framelco, has also developed a nano coated zinc oxide to prevent diarrhea in piglets.¹⁰³ However, the use of nanomaterials in animal feeds and supplements does not currently appear to be widespread.

As with fertilisers, the dominant corporate interests in the animal feed sector appear absent from the field. It isn't yet clear if they are simply marketing nano products without revealing the use of nanomaterials or if they haven't yet entered the market.

Regulators should prioritise surveying these markets and ensuring that products are both properly characterised, labelled and evaluated.

PHOTO: FIR0002/FLAGSTAFFOTOS VIA WIKIMEDIA COMMONS



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6. On the Horizon?

The nanotechnology industry regularly makes outlandish claims about what might be possible using nanotechnology. It is difficult to assess the utility, likelihood and commercial viability of many of these proposed developments, but it is worth noting some of the claims and trends in relation to food and agriculture. These include:

- A variety of nanotechnology based functional foods with fewer calories and less fat, salt, and sugar while retaining flavor and texture;
- nanoscale vehicles for effective delivery of micronutrients and sensitive bioactives;
- re-engineering of crops, animals and microbes at the genetic and cellular level;
- nanobiosensors for detection of pathogens, toxins, and bacteria in foods;
- identification systems for tracking animal and plant materials from origination to consumption;
- integrated systems for sensing, monitoring, and active response intervention for plant and animal production;
- smart field systems to detect, locate, report, and direct application of water;
- precision and controlled release of fertilizers and pesticides;
- development of plants that exhibit drought resistance and tolerance to salt and excess moisture;¹⁰⁴
- a range of uses in aquaculture, including delivery of antibiotics, anti-microbial surfaces, use of nano-sensors, stronger materials for cage and net construction and nano-foods.¹⁰⁵

Can nanotechnology 'feed the world'?

In rhetoric mirroring the GM crop debate, it has been claimed that nanotechnology can help 'feed the world'. In assessing these claims it is important to bear in mind that the world.¹⁰⁶ already produces more than enough food to meet the dietary needs of our population of 6.6 billion, but the distribution of this food is extremely inequitable.¹⁰⁷ While over 500 million people are now clinically obese,¹⁰⁸ more than 850 million people experience extreme hunger.¹⁰⁹

Over 2.5 billion people world wide rely on agriculture to make a living.¹¹⁰ However control of the global food system, valued at US\$4 trillion, is held by a small number of multinational companies.¹¹¹ Food distribution and retail sales are concentrated in the hands of a few big companies, who exert a significant influence over product supply and play a key role in determining which crops farmers grow, where - and at what price.^{112; 113}

By underpinning the next wave of technological transformation of the global agriculture and food industry, nanotechnology appears likely to further expand the market share of major agrochemical companies, food processors and food retailers.¹¹⁴

In rhetoric mirroring the GM crop debate, it has been claimed that nanotechnology can help 'feed the world'. In assessing these claims it is important to bear in mind that the world already produces more than enough food to meet the dietary needs of our population of 6.6 billion, but the distribution of this food is extremely inequitable. While over 500 million people are now clinically obese, more than 850 million people experience extreme hunger.

7. Nanofoods and nano agrochemicals pose new health risks

The incorporation of manufactured nanomaterials into foods and beverages, nutritional supplements, food packaging and edible food coatings, fertilisers, pesticides and seed treatments creates a host of new exposure pathways and a whole new array of risks for the public, workers in the food industry and farmers.¹¹⁵ However, it is extremely difficult to quantify likely exposure levels since there is no register of which nanomaterials are used and in what quantity or what food products and food contact materials they are used in.¹¹⁶

Since our 2008 report, the evidence of potential harm associated with certain nanomaterials has become stronger.

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Why nanomaterials pose new risks

- Nanomaterials are generally more chemically reactive than larger particles of the same chemicals
- Nanoparticles have greater access to our bodies than larger particles
 - Greater bioavailability and greater bioactivity may introduce new toxicity risks;
 - Nanomaterials can compromise our immune system response;
 - Nanomaterials may have long term pathological effects.

Absorption through the digestive tract

Numerous *in vivo* experiments using rats and mice have demonstrated gastrointestinal uptake of nanoparticles^{117; 118; 119; 120; 121} and small microparticles.^{122; 123; 124} Pathological examination of human tissues suggests ingestion and translocation of microparticles up to 20 µm in size.^{125; 126}

The absorption rate of substances via the gastrointestinal tract appears to depend on their properties such as size and surface structure. In one



PHOTO BY JANET STEPHENS VIA WIKIMEDIA COMMONS

study looking at rats, the smaller the nanoparticles the higher the uptake via the digestive tract.¹²⁷ In another study mice were fed 4 nm gold particles. These were later detected in the liver, kidney, spleen, lung and brain. Larger 58 nm particles remained in the gastrointestinal tract.¹²⁸

Studies have shown that nanomaterials may affect the human intestine. When human colon cells were treated with nano-sized polystyrene, which is commonly used in food packaging, these became more permeable to iron.¹²⁹ Powell *et al* have observed that the daily exposure of people in the Western world to sub-micrometre-sized mineral particles has resulted in 'pigmented cells' loaded with these particles in parts of the intestinal tract. The particles have been observed to be composed of aluminosilicates, titanium dioxide and a small percentage of non-aluminium-containing silicates such as silica (SiO₂) and magnesium trisilicate (talc).¹³⁰

Preliminary evidence suggests that existing levels of nanoparticles up to a few hundred nanometres in size in processed food may be associated with rising levels of immune system dysfunction and inflammation of the gastro-intestinal tract, including Crohn's disease.^{131; 132; 133; 134} Individuals with Crohn's disease or colon cancer have been found with nanomaterials in their intestinal tissue.¹³⁵



Nanomaterials in the human body

Our bodies' defensive mechanisms are not as effective at removing nanoparticles from our lungs, gastrointestinal tract and organs as they are with larger particles.¹³⁶ Nanoparticles are also more adhesive than larger particles to surfaces within our bodies.¹³⁷ As a result of these factors and their very small size, nanoparticles are much more likely to be taken up into our cells and tissues than are larger particles.

A growing body of evidence demonstrates that some nanomaterials are more toxic per unit of mass than larger particles of the same chemical composition.^{138; 139; 140; 141}

Nanomaterials have been detected in the heart, liver, spleen, lung, kidney, brain and bone marrow. Insoluble nanomaterials may accumulate and remain in the body for extended periods.¹⁴²

In one study, particles of 200-300 nm reached the foetus via the placenta. It is not known whether this causes harm to the placenta or the unborn child.^{143; 144} Currently there is no data on whether it is possible for nanomaterials to pass into breast milk.¹⁴⁵

The cell membrane is no obstacle to nanomaterials penetrating into cells, unlike larger particles. Studies show that 30 nm nanoparticles can even penetrate into the nucleus.¹⁴⁶

Non-degradable nanoparticles may lead to long-term health damage, even in the absence of acute toxicity. A small number of clinical studies suggest that non-degradable nanoparticles and small microparticles

which do not provoke an acute toxic response can accumulate in our bodies and over time result in the development of 'nanopathologies', such as granulomas, lesions (areas of damaged cells or tissue), cancer or blood clots.^{147; 148; 149} The Federal Institute for Risk Assessment and the Federal Environment Agency in Germany believe there is clear evidence that some nanomaterials have greater carcinogenic potential than microscale particles of the same material.¹⁵⁰

Health concerns with nanomaterials in food and food contact materials

Silica

Uses: Used as a 'trickle and flow' aid in powdered food products, as a clearing agent in beer and wine, as a food additive and a food coating.

Health concerns:

- Several recent studies have shown liver toxicity when animals were injected with nanosilica.¹⁵¹ Animal studies suggest that nanosilica can be absorbed from the gastrointestinal tract as nanoparticles, become systemically available, and accumulate in tissues. Once systemically available nanosilica appears to be mostly distributed to the liver and spleen, and to a lesser extent other tissues. Some studies suggest that nanosilica can cross the blood-brain barrier and possibly the placenta;¹⁵²
- A recent study where rats were fed synthetic amorphous silica (SAS) - a form of nanostructured silica - found that SAS caused fibrosis of the liver and that the nanostructured silica accumulated in the spleen.¹⁵³ The paper's authors have called for further studies to be done to evaluate the biological relevance of this;
- Recently a consumer intake of silica from food was estimated at 9.4mg/kg of body weight per day of which 1.8mg/kg body weight per day was estimated to be in the nano size range.¹⁵⁴

Nano-silver

Uses: In the Woodrow Wilson inventory of nano products, silver is the most common nanomaterial mentioned in product descriptions.¹⁵⁵ A recent court case in the US found that the use of nano-silver was 'ubiquitous' and that there was no way for consumers to avoid exposure.¹⁵⁶ Food and food contact products identified as containing nano-silver include baby bottles, food containers, packaging, cutting boards, salad bowls, appliances, cutlery, ice trays, filtration devices and collapsible coolers. In agriculture, it is used in poultry production and agricultural and aquacultural disinfectants.¹⁵⁷

Health concerns:

- There is mounting evidence that nano-silver may have greater toxic effects when compared with bulk silver. Nano-silver can better penetrate biological barriers and attach itself to the outside of cells.¹⁵⁸ Nanoscale silver can also enter the bloodstream and reach all organs of the body including the brain, heart, liver, kidneys, spleen, bone marrow and nervous tissue;
- Animal studies have shown placental transfer and foetal uptake of nano-silver.¹⁵⁹ This finding is disturbing when one considers a recent study which found that exposure to nanosilver caused zebra fish embryos to develop with head abnormalities and no eyes. Zebra fish have been widely used as a model organism for the study of embryological development in other vertebrates including humans;¹⁶⁰
- Health experts have also raised concerns that the widespread use of nano-silver in consumer products will further increase the problem of superbugs.¹⁶¹

Titanium dioxide

Uses: A whitener and brightener in a range of food products

Health concerns:

- ECHA is currently reviewing the safety of titanium dioxide (including the nano form) because of concerns it may be harmful to the environment and human health;¹⁶²
- In contrast to bulk particles of titanium dioxide, nanoscale titanium dioxide is biologically very active. Studies show that titanium dioxide can damage DNA,¹⁶³ disrupt the function of cells, interfere with the defence activities of immune cells and, by adsorbing fragments of bacteria and 'smuggling' them across the gastro-intestinal tract, can provoke inflammation.^{164; 165; 166; 167; 168; 169} A single high oral dose of titanium dioxide nanoparticles was found to cause significant lesions in the kidneys and livers of female mice;¹⁷⁰
- In a 2010 study the German Federal Institute for Risk Assessment (BfR) and the German Federal Environment Agency (UBA) concluded that nanoscale titanium dioxide is a possible carcinogen if inhaled;¹⁷¹

- Nano titanium dioxide is highly mobile in the body and has been detected in both humans and animals in the blood, liver and spleen.¹⁷² A study using pregnant mice found that they transfer nanoparticles of titanium dioxide to their offspring. This resulted in brain damage, nerve system damage and reduced sperm production in male offspring;¹⁷³
- A human exposure analysis of titanium dioxide through foods identified children in the 2.5-4.5 year age range as having the highest exposure because the titanium dioxide content of sweets is higher than any other food products. It also calculated that a typical exposure for a US adult may be of the order of 1 mg of titanium per kilogram of body weight per day.¹⁷⁴

Zinc oxide

Uses: Surface coatings

Health Concerns:

- Nanoscale zinc oxide (ZnO) is toxic when ingested and has been found to cause lesions in the liver, pancreas, heart and stomach.¹⁷⁵ A recent review of the safety of nano zinc oxide by the European Commission's Scientific Committee for Consumer Safety stated that "clear positive toxic responses in some of these tests clearly indicate a potential for risk to humans."¹⁷⁶ Inhalation exposure of nano zinc oxide induces lung inflammation, leading the SCCS to conclude that "the use of ZnO nanoparticles in spray products cannot be considered safe."¹⁷⁷

Copper

Uses: dietary supplements¹⁷⁸

Health Concerns:

- The German Federal Institute for Risk Assessment compared the acute toxicity of micro- and nanoscale copper. No adverse effects were observed with microscale copper – however, nanoscale copper showed adverse effects on the kidney, spleen and liver of mice.¹⁷⁹

Carbon nanotubes

Uses: While there are no confirmed commercial food and food contact products containing carbon nanotubes, food packaging and food sensors containing carbon nanotubes have been developed.^{180;181} The use of carbon nanotubes in fertilisers is also being researched but does not yet appear to have been commercialised.¹⁸²

Health Concerns:

- The Australian National Industrial Chemical Notification and Assessment Scheme (NICNAS) and Safe Work Australia, which reviewed the safety of carbon nanotubes, found that multi-walled carbon nanotubes “have been shown to induce mesothelioma in rodents.”¹⁸³

Nano supplements could cause health problems

The head of the nanotechnology research group at the United Kingdom’s Central Science Laboratory warns of unpredictable effects of nanoparticles and nano encapsulated additives: “They can be absorbed faster than desired or affect the absorption of other nutrients. We still know very little, if anything at all.”¹⁸⁴

In 2009, based on the growing number of commercially available nano supplements, the Woodrow Wilson International Center for Scholars’ project on emerging nanotechnologies found that the United States Food and Drug Administration had neither the regulatory power nor the scientific expertise to determine if these supplements were safe.¹⁸⁵

Health risks associated with nano packaging

It is possible that nanomaterials could migrate from food packaging into foods. Polymers and chemical additives in conventional food packaging are known to migrate from the packaging into food products.^{186;}¹⁸⁷ The Institute of Food Science and Technology has expressed concern that manufactured nanomaterials are already being used in food packaging, despite migration rates and exposure risks remaining unknown.¹⁸⁸ To date there are only a few studies that have investigated the migration of nanomaterials from food packaging into food and the results have been inconclusive.

Health risks posed by nano agrochemicals

There is a risk that the development of nano formulations of existing agrochemicals which are more reactive and bioactive may in turn increase the risk to human health. Many developments seem to be currently at the R&D stage and it is likely that

the agriculture sector will see some large-scale applications of nanotechnologies in the future. Should this occur, this will increase the potential exposure to agrochemicals used in the agriculture sector.¹⁸⁹ Data on the health risks associated with agrochemicals is voluminous¹⁹⁰ but scarce for nano agrochemicals. In addition to concerns relating to worker inhalation and exposure, there are concerns regarding potential risks associated with bioaccumulation of nanoparticles in food crops¹⁹¹ and the health impacts produced by interactions between both active and inactive ingredients in the new pesticide formulations.¹⁹²

Recognising that many of these nanoscale reformulations are new, EU regulation (1107/2009) requires that “coformulants must not exhibit harmful effects on human and animal health.”¹⁹³

Occupational health and safety (OHS) concerns

In the food sector, workers may come into contact with nanomaterials during production, packaging, transport and waste disposal of food and agrochemicals.¹⁹⁴ To date, there is very little data relating to the exposure of workers to nanomaterials.

A number of nanomaterials used in the food industry such as zinc oxide and titanium dioxide have been shown to be harmful when inhaled, raising OHS concerns for workers handling these materials.¹⁹⁵ However the lack of a mandatory register and product labelling means that many workers may be unaware that they are handling nanomaterials and of the need to use protective equipment.

Studies have also shown that nanomaterials can enter the bloodstream via the lungs raising major OHS concerns.¹⁹⁶

Based on a 2009 review of carbon nanotubes by Safe Work Australia and NICNAS, carbon nanotubes were declared a hazardous chemical for purposes of health and safety laws.¹⁹⁷ This ruling does not prohibit their use but means that carbon nanotubes used in the work place are supposed to be accompanied by a data safety sheet.



PHOTO BY LUIS MIGUEL BUGALLO SÁNCHEZ VIA WIKIMEDIA COMMONS

8. Environmental risks

The United Kingdom's Royal Society and Royal Academy of Engineering has called for the environmental release of nanomaterials to be "avoided as far as possible", and for their intentional release to "be prohibited until appropriate research has been undertaken and it can be demonstrated that the potential benefits outweigh the potential risks."¹⁹⁸

However, the use of products containing nanomaterials is already leading to the release of nanomaterials into the environment. Based on current trends this will increase rapidly. Waste and waste water from production, abrasion through manufacturing and use, disposal, incineration and recycling may all lead to the release of manufactured nanomaterials - as will the use of pesticides and fertilizers containing nanomaterials.

Since the publication of our 2008 report new insights into the environmental risks posed by nanomaterials have emerged, but the data is still inadequate to assess the dangers posed by the release of nanomaterials into the environment. However, a number of available studies give cause for concern.

In May 2013, a group of US scientists published the first global assessment of the likely emissions of nanomaterials into the environment and landfills. It was estimated that in 2010, 260,000–309,000 tonnes of global nanomaterial production ended up in landfills (63–91%), soils (8–28%), water bodies (0.4–7%), and the atmosphere (0.1–1.5%). According to the authors, more accurate estimates of nanomaterial emissions were hampered by the lack of available data on use.¹⁹⁹

The annual worldwide market for nanomaterials is estimated to be around 11 million tonnes. By far the largest share of the nanomaterials currently on the

market is industrial carbon (85% by weight) and silica (12% by weight). Nanoscale titanium and nano-silver are believed to be the most used nanomaterials in food and food contact materials.²⁰⁰

Anti-microbial nanomaterials now in commercial use pose serious ecological risks

Despite the limited number of studies examining the ecological effects of nanomaterials, there is already evidence suggesting that nanomaterials in commercial use by the agricultural and food industry may cause environmental harm. This is especially true for antibacterial nanomaterials such as nano-silver which is increasingly being added to food packaging and food contact materials including cling wrap, chopping boards, cutlery and food storage containers.

As the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks has noted, "the increasing use of Ag-NPs [nano-silver] in consumer and medical applications implies that they will find their way into the environment. The activity that makes them desirable as an antimicrobial agent could also pose a threat to the microbial communities in the environment."²⁰¹

Nano-silver waste that is not recycled will end up in the environment "either as solid waste in landfills, emission from wastewater treatment plants, or as residual waste from incineration plants."²⁰² One study estimated that up to 20 tons of silver from biocidal uses would be discharged to the European environment in wastewaters.²⁰³ The rapidly growing number of products containing nano-silver certainly creates the possibility of a 'mass discharge into the environment'.²⁰⁴

Impacts on aquatic ecosystems

A recent review of toxicological research on nanometal oxides silver, copper and zinc oxide reported that they are extremely toxic to freshwater aquatic organisms including fish and algae, with crustaceans being most affected.²⁰⁵

Titanium dioxide, one of the most widely used nanomaterials, caused organ pathologies, biochemical disturbances, and respiratory distress in rainbow trout.²⁰⁶ Nano titanium dioxide is also toxic to algae and to water fleas, especially after exposure to UV light.^{207, 208}

Impacts on soils

According to a US study, emissions to soils represent up to about a quarter of nanomaterial flows, mostly from the disposal of biosolids onto agricultural land. This is concerning, since studies have shown that nanomaterials can potentially harm beneficial soil microorganisms, plants, nematodes and earthworms – and prevent nitrogen fixation.^{209, 210, 211} In Australia, we produce approximately 300,000 dry tonnes of biosolids annually. Approximately 55% of this is applied to agricultural land.²¹² A recent study by Colman *et al.* found an adverse impact on plants and microorganisms in a long-term field experiment following the application of sewage biosolids containing a low dose of nano-silver.²¹³ The nano-silver treatment led to changes in microbial community composition, biomass, and extracellular enzyme activity, as well as affecting some of the above ground plant species. It also led to an increase in nitrous oxide (N₂O) fluxes. This is significant as nitrous oxide is a notorious greenhouse gas, with 296 times the global warming potential of carbon dioxide.

Any significant disruption of nitrification, denitrification or nitrogen fixing processes could have negative impacts for the functioning of entire ecosystems. There is also a risk that widespread use of antimicrobials will result in greater resistance among harmful bacterial populations.²¹⁴

Bioaccumulation of nanomaterials

A number of studies have shown that plant species can take up nanomaterials from soils.^{215, 216, 217}

This suggests a potential route for nanomaterials from sewage waste to return into the food chain. A recent report by the European Environment Agency concluded

that “the extent to which specific nanomaterials are bioaccumulative or lead to irreversible impact is largely unknown, but the current state of knowledge suggest[s] that the potential exists for such behavior under some circumstances”²¹⁸

Risks from pesticides and fertilisers with nanoscale active ingredients

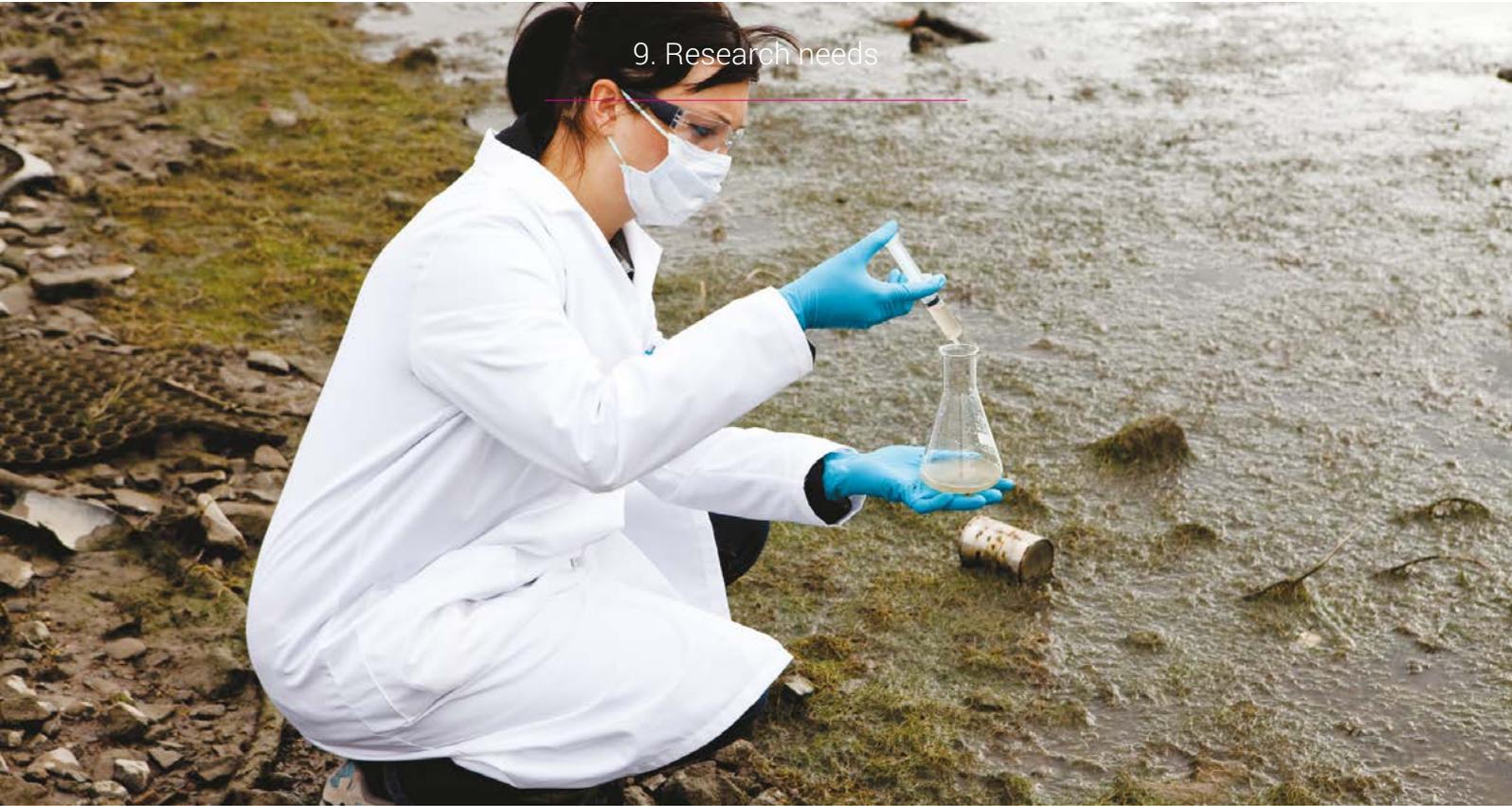
The use of pesticides with nanoscale active ingredients may pose particular risks because nanomaterials, which are more potent and behave differently to conventional chemicals, are applied in large quantities and over large areas in broadscale agriculture.

Conventional agrochemicals such as pesticides, fertilisers and seed treatments have already contributed to soil and water pollution, have caused significant disturbance of ecosystems and resulted in the loss of biodiversity.²¹⁹ There is a danger that the broad use of nano-chemicals will exacerbate existing problems.

Concerns regarding nano-fertilisers include chronic exposure of soil microbes and microfauna to levels of chemical reactivity that may be toxic and bioaccumulation of nanoparticles in soil.²²⁰ US Department of Agriculture scientists have raised concerns about the potential impacts of nanomaterials on soil bioreactivity, the effect of soil type variation on bioreactivity and the “likelihood of extreme variability in the dose-response levels between different NPs [nanoparticles] and the microbial populations that regulate plant performance.”²²¹

The claim that nano agrochemicals will reduce the overall use of pesticides should be received sceptically given similar, unfulfilled, promises made by many of the same companies in relation to genetically wmodified crops.

Nanotechnology also appears likely to intensify existing trends towards ever larger industrial scale farming operations, and an even more narrow focus on producing specialised crops.^{222, 223} This could lead to further losses of agricultural and ecological diversity.



9. Research needs

Scientists currently lack the information and tools necessary to do basic risk assessments for most nanomaterials. The European Food Safety Authority (EFSA) has admitted that risk assessments for nano-products in food and feed will inevitably have significant uncertainties, because testing methods and data on risk and exposure are missing.²²⁴

In relation to food, there are significant gaps in our knowledge including information on:

- The extent to which nanomaterials from packaging, surfaces and coatings migrate into foods;
- Where nanomaterials are distributed in the human body following ingestion;
- The long term chronic effects of ingesting nanomaterials, including impacts on sensitive populations;
- How nanomaterials interact with the human body and in the environment;²²⁵
- How and where and in what quantities nanomaterials enter the environment;²²⁶
- Once nanomaterials are released how durable they are and the extent to which they are transformed in the environment;^{227; 228}

- The fate, behaviour and ecotoxicity of nanomaterials throughout their life cycle;
- How to characterise, track and detect nanomaterials in complex environments.²²⁹

In 2012 the US National Research Council (NRC) set out an environment, health and safety (EHS) research strategy for beginning to deal with the gigantic gaps in knowledge surrounding the environmental and human health impacts of nanomaterials. That research strategy became part of the National Nanotechnology Initiative (NNI) in the US, in what was supposed to be an integrated, collaborative effort by many departments to ensure that the development of nanotechnology industries was done well.

A year later, the NRC report, *Research Progress on EHS Aspects of Engineered Nanomaterials*²³⁰, analysed progress to date. Of the 20 indicators the NRC used to assess progress, there has been little or no progress in 19.

These are not simply arcane research priorities but the basic research and knowledge that are needed both to understand, identify, assess, control and remediate potential impacts. It is the kind of knowledge that is necessary if we are going to have coherent regulation that ensures nanoproductions that aren't safe aren't released and that if unpredicted impacts occur, we have the tools to deal with them.

10. Australian Federal Regulatory Framework

Despite there being effectively no regulation of the use of nanomaterials in food and agriculture in Australia, there are a number of regulatory agencies that could regulate the use of nanomaterials in these sectors. In order for that to occur, however, regulators need to fill in the gaps in current regulations that were identified in a 2007 government commissioned review of nanotechnology and regulation.²³¹ Despite a growing body of peer-reviewed literature that suggests that potentially serious health and environmental concerns are associated with some nanomaterials, the regulatory response to nanomaterials in food and agriculture has generally been to avoid intervention.

Food Standards Australia New Zealand (FSANZ) is the primary agency responsible for ensuring the safety of food and food contact materials and for ensuring labelling requirements are followed. The agency has stated that it will require a risk assessment of “novel nano-particulates in the event that we receive an Application.”²³²

FSANZ has amended its Application Handbook so that in cases where “particle size is important in achieving the technological function or may relate to a difference in toxicity” the applicant must provide details of the nature, distribution, morphology and size-dependent properties. This applies to food additives, processing aids and nutritive substances.²³³

This sounds more useful than it is. It appears that this does not necessarily apply to foods already approved for sale in Australia but which may now contain nanomaterials.²³⁴ Equally, FSANZ has made clear that no proactive steps are being taken to ascertain whether nanomaterials in foods are already being unknowingly eaten by Australians.

FSANZ’s response to nanomaterials in food packaging inspires even less confidence. “The responsibility rests with retailers to ensure their products are safe.”²³⁵ The absence of a register means that FSANZ does not know what nanomaterials in packaging are on the market in Australia. The lack of oversight will make the detection of any potential harm to human health slower and the tracking of the cause of harm much more difficult. This standard compares poorly to EU legislation, which requires authorisation for food packaging materials and food supplements that contain nanomaterials.²³⁶

Currently, there is no requirement to label foods that contain nanomaterials. The 2011 Federal Government

food labelling review recommended labelling of products using new technologies. The Government’s entire response was, ‘not to pursue’.²³⁷

The TGA (Therapeutic Goods Association) regulates any therapeutic good, including supplements, which commonly contain nanomaterials. To date, the TGA has not regulated any nanomaterial nor have they specifically addressed the issue of nanomaterials in supplements. They note that “Therapeutic products containing nanomaterials in the form of metal oxides, liposomes, polymer protein conjugates, polymeric substances and suspensions have been registered in Australia,” but have not taken steps to assess or regulate, concluding that there is ‘no evidence’ that therapeutic goods containing nanomaterials pose a greater risk than those containing bulk sized particles.²³⁸ It is somewhat disturbing that this claim was written in 2008 and has not been updated despite significant volumes of peer reviewed work questioning that conclusion.

The APVMA (Australian Pesticide and Veterinarian Medicines Association) is responsible for nanomaterials contained in pesticides or veterinary medicines up to the point of retail sale. At that point the states become responsible. The APVMA, unlike FSANZ and other regulators has concluded that “existing substances reformulated at the nanoscale would be treated as new substances.”²³⁹

The APVMA has a registration requirement for products containing nanomaterials if they are deemed ‘novel’. They claim that “assessment of agricultural and veterinary chemicals and chemical products currently registered in Australia has not identified any to contain engineered nanomaterials”²⁴⁰ This directly contradicts the evidence presented in this report.

The APMVA has registered one animal vaccine containing nanomaterials.

The Department of the Environment is responsible for regulating releases that may impact on ‘matters of national environmental significance’.²⁴¹ They looked at the issue in 2010.²⁴² They are also responsible for advising on the environmental impacts of applications for use of nanomaterials by other agencies (such as the APVMA) but have no regulations relating to release. State Governments generally regulate waste, water treatment and most other water issues, but it appears no state has addressed the growing quantity of nanomaterial entering the waste stream.

11. Conclusion

We live in an era where public investment in science for the public good is rapidly being replaced by private investment for private interests. We live in an era where deregulation has become an ideological necessity and regulatory interventions are seen as impeding the growth of commerce - not as acts that protect the public interest.

Regulators not only resist regulation, they don't look for evidence of harm and when evidence is presented they resist, claiming uncertainty prevents them from acting – even though the uncertainty is in part a result of their own failure to act.

Contrary to the claims of a number of Australian regulators, nanomaterials are in the Australian food chain and are in agrochemicals being used in Australia. Appendix 1 lists just some of the products containing nanomaterials that are available in Australia.

Now it is up to those regulators to act and demand what they have promised – an assessment of the environmental health and safety of these nanomaterials.

The failure to treat new and powerful technologies with the kind of care that they demand is more than just a failure of regulation. It also highlights systemic problems in research and academic institutions and attitudes in industry towards risk that border on the negligent.

Nanotechnology is only one of a number of emerging powerful technologies and it is time to think about these technologies differently.

The recommendations that follow are designed to ensure that we have regulation that doesn't get left behind due to commercial pressures; that public interest science is made central to nanotechnology R&D; and that the Australian public can be active participants in making decisions about how and where nanotechnology is used in Australia.

Recommendations

- 1 A mandatory and public register of all nanomaterials and all products containing nanomaterials produced, imported and sold or used in Australia;
- 2 A moratorium on new releases of nanomaterials and products containing nanomaterials, pending a full safety assessment;
- 3 A comprehensive and precautionary regulatory regime for nanomaterials with all nanomaterials subject to environmental health and safety (EHS) assessment as new substances, even where the properties of large scale counterparts are well known;
 - Assessment must be based on the precautionary principle and the onus must be on manufacturers to comprehensively demonstrate the safety of their product. No data – no market;
 - Assessment must include a full life cycle analysis of the product;
 - Social and cultural implications of nanotechnology's expansion into food and agriculture must be addressed along with EHS assessments;
 - All relevant data related to EHS assessments and decisions made must be in the public domain.
- 4 The development and full funding of the environmental, health and safety research priorities identified by the US National Research Council;
- 5 A single agreed definition of nanotechnology based on a particle size of up to 300 nm and the specific qualities of the nanomaterial;
- 6 That all products containing nanomaterials for sale in Australia be labelled as such, ensuring consumer choice;
- 7 The public must be involved in all aspects of decision making regarding the use of nanotechnology in the food and agricultural sectors. The right to say no to nanotechnology must be ensured;
- 8 Begin the transition away from industrial agricultural and food models to a model based on sustainability.

APPENDIX 1

Table 1: Examples of food and agriculture products containing nanomaterials available in Australia

| Category | Product | Manufacturer | Nano-content | Information from manufacturer |
|---|--|---------------------|------------------|--|
| NANOMATERIALS IN FOOD PRODUCTS, INCLUDING SUPPLEMENTS | | | | |
| Additives | HDK – Silica for feed and food as a drug carrier, tableting aid, anti-caking agent. | Wacker Chemie AG | Nano-silica | Trademark issued in Australia 2003 http://www.ipaustralia.com.au/applicant/wacker-chemie-ag/trademarks/973229/ |
| Supplement | Nu-skin CoQ10 | Nu-Skin enterprises | Coenzyme Q11 | Nanotechnology Q10 as very fine particles Available from: http://www.fishpond.com.au/Health/NuSkin-Nu-Skin-Pharmanex-Nano-CoQ10/0338535211814 |
| Supplement | Nano colloidal silver | Nano Silver | Nano-silver | Antibacterial, claims to strengthen the immune system http://www.fishpond.com.au/Health/Nano-Silver-40ppm-Colloidal-Silver-350mls-Each-Bottle-Small-Particle-Size-for-Superior-Effectiveness/0091131320204?gclid=CMLUwLDDsb0CFQZ9vQodI64ATQ Also, http://oz-organic-health.com/ and http://colloidalsilverasia.com/ - supplies Australian companies |
| NANOMATERIALS IN FOOD CONTACT MATERIALS, INCLUDING PACKAGING | | | | |
| Packaging | Bairicade XT | NanoPack | Nano-clay 250 nm | Nano-clay layer for snacks, nuts, spices, sweets, coffee and tea http://www.nanopackinc.com/products.asp |

| | | | | |
|---|---|---------------------------------|---|--|
| Water filters | Water filter | Various | Nano-silver | http://www.alibaba.com/showroom/nano-silver-water-filter.html |
| Kitchen utensils | GreenPan Frying pan Thermolo | GreenPan | Polymer-ceramic-Nano-matrix | Available through various suppliers, eg www.everten.com.au/GreenPan ; www.thefind.com/kitchen/info-cookware-9.5%22-fry-pan http://www.mnn.com/food/healthy-eating/stories/is-greenpan-cookware-really-green |
| Kitchen utensils | Cookware with nanosilver | Various | Nano-silver | http://www.tradekorea.com/products/2211/1/NANO_SILVER.html |
| Cleaning products | Zielotex cleaning cloth | Zielonka | Nano-silver | http://www.alibaba.com/showroom/nano-silver-cloth.html |
| Coating | Nanopool | Nanopool | Nano-silica 100 nm | Antibacterial coatings for tablecloths, oven, grill and refrigerators |
| NANOMATERIALS IN AGRICULTURAL PRODUCTS | | | | |
| Agrochemical | Headway MAXX Banner MAXX Fungizid | Syngenta | Unspecified nano content | These pesticides are marketed as micro-emulsions. |
| Agrochemical | Nano-Gro | Agro Nanotechnology Corporation | Unspecified nano content | "the first plant growth stimulator based on nanotechnology" http://www.agronano.com/nanogro.htm |
| Vitamins for animals | KER | Nano-E | Nanodispersed vitamin E to be added to food | http://www.vetnpetdirect.com.au/kerx_nano_e |

Table 2: Examples of products in the food and agriculture sectors containing nanomaterials produced in Australia

| Category | Product | Manufacturer | Nano-content | Information from manufacturer |
|---|--|---------------------------|--|---|
| NANOMATERIALS IN FOOD PRODUCTS, INCLUDING SUPPLEMENTS | | | | |
| Supplements | Nano-glutamine, nano creatine | Advanced Sports Nutrition | Unspecified nano content | http://www.asn-nutrition.com.au/index.php/products/item/nano-glutamine |
| Nano encapsulation, nano-particles | Product names not provided on website | Herames | Nano-silver, silica, silica oxide, alumina-oxide, titania-titanium-dioxide | http://www.hermesco.net/nano-structures.html |
| NANOMATERIALS IN FOOD CONTACT MATERIALS, INCLUDING PACKAGING | | | | |
| Coatings | Liquid nano glass | Nanopools | Silicon dioxide | http://www.businessinsider.com.au/million-dollar-idea-spraying-liquid-glass-on-clothes-and-furniture-creates-an-instant-stain-and-bacteria-shield-2011-3 |
| Coatings | DIY coatings for surfaces including kitchens | Nanokote | Unspecified nano content even in safety data sheet | http://www.nanokote.com.au/n/glass-ceramics SDS: http://www.nanokote.com.au/downloads/File/pdf/MSDS-Nanokote-Glass-and-Ceramics-Coating-DIY-Kit.pdf |
| Packaging | Fresh Produce Bags | | Unspecified nano content | http://www.centurymail.com.au/shopping/kitchen/ Promises 30 days extra shelf-life |
| Packaging | Packaging boxes | Nanobox | Nano-silver | http://www.gohospitality.com.au/c/Hopack/Nanobox-Paper-Food-Packaging-by-Hopack-p101019 |
| NANOMATERIALS IN AGRICULTURAL PRODUCTS | | | | |
| Agrochemical | Herbagreen, Vitaflora (plant nutrients and fertilisers) Nanofeed, megamin (animals supplements) | Nano Growth Technologies | Unspecified nano content | http://www.ngtech.com.au/www.ngtech.com.au/index.htm |
| Anti-bacterials for animals | | Herames | Unspecified nano content | http://www.hermesco.net/bio-and-medical.html |

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