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Title: General Insights on Issues Emerging from Food Applications

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1.0 Introduction

Rapid advancements in nanosciences and nanotechnologies in recent years have opened up new prospects for so many industrial and consumer sectors that they have been regarded as the hotbed of a new industrial revolution. The food sector, which itself is worth around 4 trillion US\$ per annum globally, is an obvious and prime target of these new developments. The current level of applications in food and related sectors is, however, new emergent. The initial focus of nanotechnology applications has been on food packaging and health-food products, with only a few applications so far in the mainstream food and beverage areas. Although the number of available products has steadily increased worldwide over recent years, most applications are still at R&D or near-market stages. The information relating to the current scale of commercial activity in this field is also very patchy. Because of this, estimates of the current and future market size of nanotechnology-enabled food products vary widely. In 2006, the global market value for nano-enabled food and food packaging products was estimated at around US\$4 billion, predicted to range between US\$6 billion by 2012² and >US\$20 billion by 2010³. According to the estimates, food packaging applications form the largest share of the current and short-term predicted market for nano-enabled products in the food sector. The most promising growth areas identified for the near-future include ‘Active’ and ‘Smart’ packaging, health-foods, and functional food products. Reports have also suggested that the number of companies undertaking R&D in food related applications could be between 200 to 400^{2,4}, including some major international food and beverage companies. It is widely expected that there will be many more new developments in the coming years, and that it could have a major impact on the whole of agricultural and food sectors.

Market reports suggest that the nanofood sector is currently led by the USA, followed by Japan and China, whereas Asian countries (led by China) have been predicted to be the biggest future market for nanofood products³. Considering the fact that rapid advancements in nanotechnologies have also raised a number of technological, health and safety, regulatory and societal issues, it is likely that the developing countries will lag behind the developed world in terms of technical knowledge and expertise, production/ processing capacity, quality control, safety assessment, regulatory controls etc. It is also possible that because of less well developed regulatory and other control systems, developing countries will offer a more open market for nano-food products in the future.

2.0 Current state of developments

2.1 Applications for food production

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² Cientifica Report. 2006. “Nanotechnologies in the Food Industry” published August 2006.
www.cientifica.com/www/details.php?id=47.

³ Helmut Kaiser Consultancy, Study: nanotechnology in food and food processing industry worldwide 2003–2006–2010–2015, 2004, available at www.hkc22.com/Nanofood.html.

⁴ Institute of Food Science and Technology (IFST) Trust Fund. 2006. Nanotechnology information statement
www.ifst.org/uploadedfiles/cms/store/attachments/nanotechnology.pdf.

The main applications of nanotechnologies for food production include the potential use of nano formulated agrochemicals (e.g. fertilisers, pesticides, veterinary medicines) for improved efficacy, less use of farm chemicals, better control of applications (e.g. slow release pesticides), safer animal feeds (e.g. fortified with nano-supplements, antimicrobial additives; detoxifying nanomaterials), and nano-biosensors for animal disease diagnostics. Example applications include nano-sized feed supplements (vitamins, minerals), feed additive such as a biopolymer derived from yeast cell wall that can bind mycotoxins to protect animals against mycotoxicosis, and an aflatoxin-binding nano-additive for animal feed derived from modified nanoclay⁵. Another example is polystyrene nanoparticle with polyethylene glycol linker and mannose targeting biomolecule that can potentially bind and remove food-borne pathogens in animal feed.⁶ Nano-encapsulated and solid lipid nanoparticles have also been explored for the delivery of agrochemicals.⁷ However, despite a great deal of interest in the possible use of nanotechnologies in food production area, examples of the available products at present are still very scarce, and most developments in this area seem to be currently at R&D stage. Such applications, nevertheless, have the potential for adoption at a very large-scale by the agricultural sector worldwide. In view of this, it is important to develop adequate risk management strategies, because some of the applications (e.g. nano-pesticides) may pose a risk to farm workers, the environment, and the consumers through potential carryover of residues in food products.

2.2 Applications for Food Processing

The main applications for the food processing area include the use of nano food ingredients/additives in the form of:

- processed food nanostructures for improved or new tastes, textures, mouth-feels. Nano-structuring of natural food materials can potentially enable the use of less fat but still better tasting food products. A typical product in this technology would be a nano-structured ice cream, mayonnaise or spread, which is low-fat but as “creamy” in texture as the full-fat equivalent. Such products would therefore offer a ‘healthy’ option to the consumer.
- nano-sized or nano-encapsulated food additives and supplements for improved dispersibility of fat-soluble additives in food products, improved or new food tastes, hygienic food storage, reduced use of fat, salt, sugar and preservatives; enhanced uptake and bioavailability of nutrients and supplements. Currently available examples include vitamins, antioxidants, colours, flavours, and preservatives. Also developed for use in food products are nano-sized carrier systems for nutrients and supplements. These are based on nanoencapsulated substances in liposomes, micelles or protein based carriers. The nano-carrier systems are also used for taste masking of certain ingredients and additives, or to protect them from degradation during processing. Examples include food additives, such as a synthetic form of the tomato carotenoid (lycopene), benzoic acid, citric acid, ascorbic acid, and supplements such as vitamins A and E, isoflavones, β -carotene, lutein, omega-3 fatty acids, coenzyme-Q10.

⁵ YingHua, S., ZiRong, X., JianLei, F., CaiHong, H., MeiSheng, X. (2005) In vitro adsorption of aflatoxin adsorbing nano-additive for aflatoxin B1, B2, G1, G2, *Scientia Agricultura Sinica*, 38 (5) 1069-1072.

⁶ Kuzma, J., Romanchek, J. & Kokotovich, A. 2008. Upstream oversight assessment for agrifood nanotechnology. *Risk Anal.*, 28: 1081–1098

⁷ Frederiksen, H. K., Kristensen, H. G. and Pedersen, M. (2003) Solid lipid microparticle formulations of the pyrethroid gamma-cyhalothrin-incompatibility of the lipid and the pyrethroid and biological properties of the formulations. *J Control Release* 86 (2-3): 243-52.

- A few inorganic nanomaterials may potentially be used in (health)food products. These include transition metals (e.g. silver, iron, titanium dioxide); alkaline earth metals (e.g. calcium, magnesium); and non metals (e.g. selenium, silicates). Food packaging is currently the major area of application of metal and metal-oxide nanomaterials. Examples include plastic-polymer composites with nano-clay for gas barrier, nano-silver and nano-zinc oxide for antimicrobial action, nano-titanium dioxide for UV protection, nano-titanium nitride for mechanical strength and as a processing aid, nano-silica for hydrophobic surface coating etc. The use of nano-silver as an antimicrobial, antiodorant, and a (proclaimed) health supplement has already surpassed all other nanomaterials used in different sectors.⁸ The current use of nano-silver is mainly for health-food and packaging applications, but its use as an additive in antibacterial wheat flour is the subject of a recent patent application.⁹ Nano-silica is reported to be used in food contact surfaces and food packaging applications, and some reports suggest its use in clearing of beers and wines, and as a free flowing agent in powdered soups. The conventional bulk forms of silica and titanium dioxide are permitted food additives (SiO₂, E551, and TiO₂, E171), but there is a concern that the conventional forms may also contain a nano-sized fraction due to natural size range variation.¹⁰ A patent (US Patent US5741505) describes nano-scale inorganic coatings applied directly on food surface to provide moisture or oxygen barrier and thus improve shelf life and/or the flavour impact of foods. The materials used for the nano-coatings, applied in a continuous process as a thin amorphous film of 50 nm or less, include titanium dioxide. Another example is that of nano-selenium, which is being marketed as an additive to a tea product in China for a number of (proclaimed) health benefits.
- Surface functionalised nanomaterials are being developed that may add a certain functionality to food or packaging products. Current examples include the use of organically-modified nanoclays in food packaging applications. However, due to the possible convergence of nanotechnologies with other technologies (e.g. biotechnology), the development of new functionalised nanomaterials is likely to grow in the future.

2.3 Applications for Food Packaging

Whilst most nanotechnology applications for food and beverages are currently at R&D or near-market stages, applications for food packaging are rapidly becoming a commercial reality.¹¹ Food packaging applications form the largest share of the current and short-term predicted market for nano-enabled products in the food sector. **Error! Bookmark not defined.** It has been estimated that nanotechnology-derived packaging (including food packaging) will make up to 19% of the share of nanotechnology-enabled products and applications in the

⁸ Woodrow Wilson International Centre for Scholars (2008) The Nanotechnology Consumer Inventory Available at: www.nanotechproject.org/inventories/consumer/, accessed 16 September 2008.

⁹ Park K.H. (South Korea) Preparation method antibacterial wheat flour by using silver nanoparticles, Korean Intellectual Property Office (KIPO) Publication number/ date 1020050101529A/ 24.10.2005.

¹⁰ EFSA - European Food Safety Authority (2009) Scientific Opinion on 'The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety', Scientific Opinion of the Scientific Committee, adopted on 10 February 2009, The EFSA Journal (2009) 958, 1-39.

¹¹ Chaudhry, Q., Castle, L. and Watkins, R. (Editors) (2010) Nanotechnologies in Food, Royal Society of Chemistry Publishers (ISBN 978-0-85404-169-5).

global consumer goods industry by 2015.¹² The main applications of nanotechnologies for food packaging include the development of nanomaterial-polymer composites for:

- Improved packaging properties (flexibility, durability, temperature/ moisture stability, gas-barrier properties)
- ‘Active’ packaging: polymers incorporating nanomaterials with antimicrobial properties
- Nano-coatings to develop hygienic food contact surfaces and materials, and hydrophobic coatings for self-cleaning surfaces
- Nano-(bio)sensors for ‘Smart’ packaging concepts

Examples include plastic polymers with nano-clay as gas barrier, nano-silver and nano-zinc oxide for antimicrobial action, nano-titanium dioxide for UV protection, nano-titanium nitride for mechanical strength and as a processing aid, nano-silica for surface coating etc.

2.4 Other applications

Other applications of nanotechnologies that might impact on food safety and quality include the use of nano-porous materials for water filtration and for removal of undesirable tastes, flavours or allergens; certain nanomaterials (e.g. zero valent iron) for water decontamination, nano-coatings (e.g. of titanium dioxide) for photocatalytic sterilisation of surfaces and water, nano(bio)sensors for food safety; and nano-barcodes for food authenticity.

3.0 Main projected benefits

The main projected benefits of nanotechnology applications for the food sector include

- More efficient food production methods – less use of agrochemicals (e.g. pesticides, antibiotics; less harm to the environment; less carryover of harmful chemicals residues in food);
- More hygienic food processing (better food safety and quality);
- Novel food products with improved tastes, flavours, mouth feels (healthy/ nutritious/ tasteful food products);
- Food products with less (or no) preservatives;
- Longer shelf-life of food products (less food waste);
- Innovative lightweight, stronger, functional packaging;
- ‘Smart’ labels to ensure food authenticity, safety, and traceability.

3.1 Potential risks of nanotechnology applications for the food sector

Currently there are major knowledge gaps in our understanding of the properties, behaviour and effects of the nanomaterials that are (or may be) used for food applications. These knowledge gaps make it difficult to assess the risk of such applications to a consumer, although a careful consideration of the nature of materials and applications can provide a

¹² Nanoposts report, Nanotechnology and Consumer Goods – Market and Applications to 2015, 2008, published by Nanoposts.com.

basis for a conceptual risk categorisation. For example, products containing natural food nano-structures that are likely to be digested/degraded may not require as detailed an evaluation as the products containing insoluble and potentially biopersistent nanomaterials. On the basis of this, the following broad application categories may be considered:

- Areas of least concern: Processed (natural) nano-structures in food, that are solubilised or digested in the gastrointestinal tract, and are non-biopersistent.
- Areas of some concern: Nano-carrier systems for food/feed additives that may not be biopersistent but may carry the encapsulated substances across the GI tract. The tissue distribution of the materials contained in such nano-carriers may be different from that of conventional equivalents. An increased bioavailability of some additives (e.g. some preservatives) may lead to increased health risk.
- Areas of major concern: The use of insoluble, indigestible, and potentially biopersistent nano additives (e.g. some metals/oxides), and the potential use of functionalised nanomaterials in food products. These applications may pose a potential exposure to insoluble biopersistent nanoparticles, or functional nanomaterials – the ADME and toxicological properties of which may not fully known at present. Some of the projected applications in the agricultural sector (e.g. nano-pesticides) will also fall in this category.

It is of note that acutely toxic materials are not likely to be used knowingly in food products. The main concerns over consumer safety therefore relate to long term/ new or unforeseen harmful effects of exposure to nanomaterials. Nano-additives in food are also likely to undergo a number of transformations in food and the gastrointestinal system due to agglomeration, aggregation, binding with other food components, and reaction with stomach acid, enzymes, and other biotransformation in the body. Such transformation are likely to change the uptake and bioavailability of the materials in the body. However, there is currently little understanding of the impact of such transformation on the safety of nano-food products.

Any potential risk arising from nanotechnology-derived food contact materials will be dependent on the migration behaviour of nanomaterials from packaging. The few experimental and modelling studies carried out so far^{13,14,15} suggest the likelihood of nanomaterial migration from polymer packaging to be either nil or very low. On the basis of modelling,¹⁶ it can be predicted that any detectable migration of nanoparticles from packaging to food can only take place where very small nanoparticles (in the lower nm range) have been incorporated in a polymer matrix that has a relatively low dynamic viscosity, and the particles are not bound to the polymer matrix. This provides some reassurance in the safety of nanotechnology-derived food contact materials.

¹³ Avella, M., De Vlieger, J.J., Errico, M.E., Fischer, S., Vacca, P., and Volpe, M.G. (2005) Biodegradable starch/clay nanocomposite films for food packaging applications. *Food Chemistry*. 93: 467-474.

¹⁴ Bradley, E.L., Castle, L. and Chaudhry, Q. Nanoparticles in food contact materials and articles, 2010, in preparation.

¹⁵ EFSA (2008) 21st list of substances for food contact materials, Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) (Question No EFSA-Q-2005-151, EFSA-Q-2006-324, EFSA-Q-2006-323), Adopted on 27 November 2008, *The EFSA Journal* (2008) 888-890, 1-14.

¹⁶ Šimon, P., Chaudhry, Q., and Bakoš, D. (2008) Migration of engineered nanoparticles from polymer packaging to food – a physicochemical view, *Journal of Food and Nutrition Research* 47(3): 105-113.

4.0 Regulatory aspects

A number of reviews have shown that developments in nanotechnologies are not taking place in a regulatory vacuum, as the potential risks will be controlled under the existing frameworks.¹⁷ The current regulatory frameworks for food and food contact materials in different jurisdictions, such as the European Union, the United States, and Australia are broad enough to ‘capture’ nanotechnology applications in the food sector. These include regulations relating to general food safety, food additives, novel foods, specific health claims, chemical safety, food contact materials, water quality, and other specific regulations on the use of certain chemicals in food production/ protection, such as biocides, pesticides, veterinary medicines etc.¹⁸ The environmental regulations are also likely to capture the use of nanotechnologies in food packaging, and agri-food production applications.

5.0 Current major gaps in knowledge

- A clear, fit-for-purpose, definition of nanomaterials and technologies is lacking. It is being considered at the moment under the recast of the food laws in Europe.
- Validated methods for detection and characterisation of nanomaterials in complex food matrices are not available. A few research projects are currently underway in this area.
- Toxicological research on nanomaterial safety is in its infancy. Some common themes have, however, started to emerge from research projects that are underway in this area. This knowledge needs to be periodically pooled and reviewed to draw some conclusions.
- ADME profiles of nanomaterials may be different from bulk equivalents, and it is not known how the ingested nanoparticles will behave in the body. Again research in this area is at early stages.
- The long term health consequences (if any) of ingestion of insoluble and biopersistent nanoparticles via food are unknown.
- There is little understanding of the potential emergence of functional nano(bio)materials through the convergence of nanotechnologies and biotechnologies.
- Guidance on risk assessment methodologies is patchy. In Europe, an EFSA Working Group is currently working on this.
- There are some uncertainties over regulatory control of nanotechnology-enabled food products. For example, over clearly defined responsibility/ liability for relevant products and applications, appropriate permissible limits that relate to the (potential) effects of nano-substances in food, and an exclusive premarket approval system for nano-enabled food products. There are some regulatory developments currently in the pipeline – e.g. the recast of the key European regulatory instruments, such as Regulation 258/97 (the Novel Foods Regulation), which is expected to include a specific reference to foods modified by new production processes ‘such as nanotechnology and nanoscience, which may have an impact on food’.

¹⁷ Gergely A (2007) Regulation of nanotechnology – within REACH? Nano Now February, 44-46.

¹⁸ Gergely, A., Bowman, D. and Chaudhry, Q. (2010) Small Ingredients in a Big Picture: Regulatory Perspectives on Nanotechnologies in Foods and Food Contact Materials, In Nanotechnologies in Food, Chaudhry, Q., Castle, L. and Watkins, R. (Eds), Royal Society of Chemistry Publishers (ISBN 978-0-85404-169-5).

6.0 Options for addressing the challenges

- Establishment of international research networks that can address different aspects of the existing and new nanotechnology applications in agriculture and food sectors – i.e. not only the benefits but also the potential risks to the consumer and the environment.
- Development of clear and consistent guidelines for risk assessment of nano-food products.
- Establishment of a global body that can ensure quality control (i.e. a product indeed has been derived from nanotechnologies and not just labelled for a commercial gain – or vice versa), and safety of nano-food products.
- Promotion of industry best practices and self-regulation in the use of nanotechnologies for food and related applications.
- Appropriate regulatory system at the global level that ensures pre-market evaluation of nano-food products, sets liabilities, and sets clear limits for any nano-additives in food and related applications.
- Possible labelling of nano-food products to inform the consumer.

7.0 Conclusion

An overview of nanotechnology applications in the food and related sectors shows that they offer a variety of benefits to the whole of food chain – from new and improved tastes, textures, to a potential reduction in the dietary intake of fat and other food additives, improved absorption of nutrients and supplements, preservation of quality and freshness, and better traceability and security of food products. The current level of application in the food sector is, however, only small and most products and applications are still at R&D stage. The possible use of some insoluble and potentially biopersistent nanomaterials in food products has also raised concerns over their safety to consumer health and the environment. At present, there are a number of major knowledge gaps in regard to our understanding of the properties, behaviour and effects of nanomaterials. The existence of stringent regulatory controls in many countries provides some reassurance that only safe products and applications of nanotechnologies will be permitted on the market. However, there is a need for a pragmatic approach to a case-by-case pre-market safety evaluation of the nanotechnology-derived food products.

Title: Nanosized and nanomaterial based (bio)sensors- Nano2Biosensors

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Introduction

Detection and identification of pathogenic microorganisms and toxins in foods are the essential steps to initiate the process of Risk Analysis to mitigate food safety risks. Biosensors, originated from the integration of molecular biology and information technology, could provide inspectors, food processing operators and food safety authorities with the ability to rapidly detect pathogens and potential contaminants, including chemical/biological agents. Enhanced screening and surveillance of food sources will significantly improve food safety, thereby reducing the health risks and medical costs associated with foodborne illness.

Despite the recent advances in food pathogen detection, there still exist many challenges and opportunities to improve the current technology in order to have simple, rapid, versatile, and inexpensive tools for detection of food contaminants. In these recent years the advent of nanotechnology applications in Food safety (i.e. detection systems, biosensors etc) is becoming a key focus of research and development, and the potential benefits of this emerging technology are receiving growing attention from both the public and the private sector. In this context of special interest are the ‘nanosized’ and nanomaterial (macrosized) based biosensors - Nano2Biosensors – a modern and efficient class of detection systems. The application of Nano2Biosensors in food industry could lead to immense improvements in quality control, food safety, and traceability. The advantages of Nano2Biosensors can lead to their use in various food industry processes: from raw material preparation, food processing (quality control), monitoring of storage conditions etc. doing these devices able to act as cost effective tools for quality & process controls as well as ensure food safety.

Advantages of Nano2Biosensors

A large range of biosensors are already available for laboratory use. Several ‘Nanosized’ and nanomaterial (macrosized) based biosensors – called here Nano2Biosensors- based on optical and electrical techniques are developed. These are based on nanoscience and nanotechnology related concepts and materials. Nano2Biosensors have a great potential for application in food analysis, in both quality and safety control. Nano2Biosensors can be used to detect several compounds: DNA, protein, cells or pollutants such as heavy metals, pesticides etc. Some interesting Nano2Biosensors based on the use of nanoparticles and techniques such as optical microscopy (i.e. based in light absorption, scattering, fluorescence of nanoparticles) and electrochemistry (i.e. stripping analysis, potentiometry etc.) have been developed and reported in several journal publications (even by our group) and patents.

Nano2Biosensors can achieve very low detection limits (even single molecule or cell). In addition they offer multidetection possibilities and may ensure a high stability (i.e. nanoparticles such as quantum dots are more stable than enzymes or fluorescence dyes). The main advantage beside the reduction of reagent volumes, detection time, keeping the same sensitivity, is the user-friendly applicability: there is no need for professional users. The idea is to develop one-push button like devices that can give a fast ‘yes-no’ response or ensure a similar simple communication with the end-user.

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Due to the miniaturization and mass production possibilities (micro & nanofabrication, nanomaterial synthesis etc.) lower cost Nano2Biosensors can be fabricated ensuring at the same time the required efficiency for applications in food field. The assumptions that need to be met for this direction of development seem to be related to investment and market. A strong cooperation between research groups / institutes and companies is necessary.

Costs and technical capacity/knowledge needed to apply the technology

Nano2Biosensors technologies fit very well to user-friendly and in-field application devices (including implanted devices that can be used to monitor inside food/bioprocess reactors and mostly, theoretically even inside living organisms, plants for basic studies). These biosensors can be applied in different ways. This would depend on the food area, analyte to be detected, frequency of measurements as well as other factors that as a whole would affect the cost. If a mass production of these devices would be achieved cost issues would be overcome and consequently the accessibility to this technology and its products in general and especially for developing countries wouldn't be an important issue.

Scientific and technological barriers / obstacles

Several scientific and technological barriers and obstacles must be overcome before the Nano2Biosensors' benefits can be effectively used realized in contaminants detection in real food systems. The developed Nano2Biosensor are shown to be excellent tools for laboratory applications but due to reproducibility problems as well as interferences their application in real samples is still limited. The identification of major disadvantages would depend on the application. For example the detection of DNA using simple biosensors cannot be compared in terms of sensitivity by standard / laboratory conventional /methods that use i.e. PCR.

Problems related to the risks to human health and environmental need to be carefully considered. Usually, as all the other assays that involve a variety of chemicals /reagents safety issues need to be considered. Especially for biosensors based on nanomaterials there is a lot of concern related to the toxicity of these materials (i.e. nanoparticles, nanowires, carbon nanotubes etc.). The evaluation of these effects is still in process. It needs a careful study overall for in-vivo uses so as to achieve right conclusions.

Strategies to overcome the challenges

To overcome the challenges of Nano2Biosensor technology and its applications in food field a more detailed study related to interferences for real sample analysis as well as technological aspects related to final application (the interested analyte to be detected) need to be addressed.

Point strategies to overcome the challenges should be:

In-field applications. In-field applications of Nano2Biosensor still need a big effort so as to overcome problems related to applications in real samples. Avoidance of interferences coming from sample matrix is the key point for success.

Detection limits. Reaching of low detection limits (detection of few molecules, cells) in a relatively high volume of samples (i.e. 1 molecule or 1 cell in 1mL food sample) needs the

development of fast and efficient preconcentration tools/routes based on nano & microfabrication.

Market opportunities. The entrance of Nano2Biosensors in food market needs to overcome the general cost/efficiency/applicability parameters. Industries (big/small?) and other agencies investments in Nano2Biosensor is crucial.

The expected timelines for development

The timelines for development would depend on the kind of application as well as funding of research / application /technological development projects. This may take from one to several years. For example sensors for mycotoxins (i.e. aflatoxin) are being developed. These are based on various biosensing transduction modes (i.e. electrochemical such as amperometric etc. or optical such as surface plasmon resonance etc.) and assays principle (immunoassays, enzymatic inhibition etc.). Nevertheless areas where there does not seem to be a lot of promise for the Nano2Biosensors technology are in-situ applications (i.e. implanted sensors) seem to be still difficult due to stability issues. The most important difficulties are related to the stability of biological materials used as receptors (i.e. enzymes, antibodies, cells).

Conclusions

We are in terms of addressing some of the challenges related to Nano2Biosensor technology and its application in food related fields. For sensors related to *in-field* applications (bringing the sample to the sensor, or insert sensor inside the sample during a determined period of time) we are almost in time but for *in-situ* (implanted sensor for long term / automatic monitoring inside the process / plants) ones still there is a relatively long way.

Some of the Nano2Biosensors technologies (i.e. electrochemical sensors, lateral flow) do not require a lot of investment and high tech instrumentation for research. Developing countries are in fact involved in these kinds of researches & applications which would do them very good candidates for a fast approaching of these technologies.

The application of these sensing systems would have a globally effect with a special impact for developing countries. This would be related to the security of food and food processing not only for the security of local people but also for others being visitors in these countries or importing foods from these countries. The quality indicators tested *in-situ* through biosensing systems would be an added value of the food products being exported to other places in the world. This would also highly benefit the developing countries due to a faster and more efficient processing of food products.

**Title: Nanotechnology-Enabled Water Treatment and Reuse for Developing Countries:
Emerging Opportunities and Challenges**

Name: Pedro J.J. Alvarez¹, Qilin Li and Jonathan Brame

Introduction

Ensuring reliable access to inexpensive and clean sources of water is an overriding global challenge noted as one of the Millennium Development Goals of the United Nations. This challenge is rapidly growing as the world's population increases; global climate change threatens to take away a large fraction of already scarce fresh water resource due to seawater intrusion; agriculture and food production draws more and more of the potable water supply; and larger quantities of water are used to produce increasing amounts of energy from traditional sources.

The need for a sustainable and safe water supply is particularly compelling for developing countries not only in rural villages but also in rapidly growing metropolitan areas, due to the faster tendency towards mega-urbanization coupled with a lack of adequate infrastructure to purify water and wastewater. The high energy consumption and risks associated with water quality deterioration during water distribution through aged centralized systems call for both a paradigm shift in water management and for technology reform.

Vision for Distributed Nanotechnology-Enabled Water Treatment and Reuse

Nanotechnology can enable a distributed water reuse and treatment paradigm and offer leapfrogging opportunities to obviate concerns of water quality degradation within distribution networks, alleviate dependence on major system infrastructure, exploit alternative water sources (e.g., recycled "new water") for potable use, and abate energy consumption. Future urban systems will increasingly rely on high-performance nanotechnology-enabled water monitoring, treatment and reuse systems that target a wide variety of water pollutants and are affordable and easy to operate. This will also contribute towards a zero discharge paradigm, which is the ultimate goal of sustainable urban water management. Examples of engineered nanomaterials (ENMs) that can enable this vision are summarized in Table 1. Such novel technologies for water treatment at both point-of-use and community scale are of great value for increasing the robustness of urban water distribution networks, for neighborhoods and buildings that are not connected to a central network, and for emergency response following catastrophic events.

Examples of Research and Development Activities

Although nanotechnology-enabled water treatment and reuse is still far from full-scale application, there is considerable lab scale research activity that has yielded promising results, and several pilot-scale and commercial applications are beginning to emerge (Radjenovic *et al.* 2009, Haldane 2010, He *et al.* 2010). Engineered nanomaterials (ENMs), primarily silver nanoparticles, have been used in household water filters. Current research on nanotechnology enabled water treatment has focused on four major areas: 1) Adsorptive removal of pollutants; 2) catalytic degradation; 3) disinfection and microbial control; and 4) membrane filtration and desalination (Li *et al.* 2008).

Nanomaterials can be superior adsorbents because of their extremely high specific surface area. Magnetic nano-adsorbents are particularly attractive as they can be easily retained and separated from water. The high adsorptive efficiency of magnetite nanoparticles can be used for removing heavy metals (e.g., arsenic) and radionuclides from water. The super-paramagnetic properties of nano-magnetite allow separation under low magnetic fields

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to enable recycling and reuse. This technology was selected by Forbes magazine as one of the top five nanotechnology breakthroughs of 2006, and is currently being tested by Rice University at the pilot scale in sand filters in the city of Guanajuato, Mexico.

Table 1. Opportunities for ENM in Water Treatment and Reuse

<i>Desirable Properties</i>	<i>ENM</i>	<i>Examples of ENM-Enabled Technologies</i>
Large surface area to volume ratio		Superior sorbents with high, irreversible adsorption capacity (e.g., nanomagnetite to remove arsenic and other heavy metals)
Enhanced catalytic properties		Hypercatalysts for advanced oxidation (TiO ₂ & fullerene-based photocatalysts) & reduction processes (Pd/Au to dechlorinate TCE)
Antimicrobial properties		Disinfection without harmful byproducts (e.g., enhanced solar and UV disinfection by TiO ₂ & derivatized fullerenes), surface nanopatterning for biofouling control
Multi-functionality (antibiotic, catalytic, etc.)		Fouling-resistant (self-cleaning), functionalized filtration membranes that inactivate virus and destroy organic contaminants
Self-assembly on surfaces		Surface structures that decrease bacterial adhesion, biofilm formation and corrosion of water distribution and storage systems
High conductivity		Novel electrodes for capacitive deionization (electro-sorption) and low-cost, energy-efficient desalination of high salinity water
Fluorescence		Sensitive sensors to detect pathogens and other priority pollutants

Many nanomaterials have (photo)catalytic properties that can be used for oxidative or reductive degradation of chemical pollutants as well as disinfection. Potent bacterial and viral inactivation capacity has been demonstrated for functionalized fullerenes and TiO₂-based nanocomposites in the presence of visible and UV light (Lee *et al.* 2009). This approach represents a significant improvement over current chemical disinfection methods that produce harmful disinfection byproducts and are ineffective to disinfectant-resistant pathogens such as *Cryptosporidium* and *Giardia*. The same process can be used to treat recalcitrant pollutants such as pharmaceutical compounds and endocrine disruptors. Superior (hyper)catalysts, consisting of palladium-coated gold nanoparticles, have also been developed to promote rapid dechlorination of organic solvents such as trichloroethylene.

The remediation of groundwater contaminated by oxidized pollutants can be significantly enhanced by the use of nano-scale zerovalent iron (NZVI), a powerful reductant ($E_h^\circ = -409$ mV) that can be used to dechlorinate TCE or reductively immobilize some heavy metals such as Cr(VI) or radionuclides such as U(VI). Pilot field studies have demonstrated the feasibility to inject NZVI into contaminated aquifers to create reactive zones or permeable reactive iron that intercept and destroy priority pollutants (He *et al.* 2010). NZVI is particularly attractive for source-zone remediation.

Biofilm formation in water distribution and storage systems harbors pathogens, causes biocorrosion and increases energy consumption. A promising approach to prevent these problems without formation of disinfection byproducts or use of toxic biocides is to create biofouling resistant surfaces by manipulating surface physical structures at the micro and nano scale, a mechanism used by marine organisms (dolphins and sharks) and plants (lotus leaf) to prevent bioadhesion. A combination of advanced photolithography, nanoparticle surface assembly and novel nano-template based methods could be used to create surface patterns that inhibit bacterial adhesion (Nel *et al.* 2009).

Development of multifunctional membranes is another area where nanotechnology may revolutionize water treatment. The application of membranes for drinking water and wastewater treatment is rapidly growing. Especially for areas where fresh water supply is limited, the need for brackish ground water and seawater desalination as well as potable reuse

of wastewater requires high-efficiency membrane systems. In spite of the advantages membrane systems offer, the inherent problem of membrane fouling, e.g., scaling, organic fouling and biofouling, poses the biggest obstacle to their broader application. In addition, the large plethora of contaminants in water and the diversity in their properties usually requires multiple stages of treatment. Incorporation of functional (e.g., adsorptive, (photo)catalytic and antimicrobial) nanomaterials into water treatment membranes offers the opportunity to achieve multiple treatment goals in a single step while protecting membranes from fouling. For example, when irradiated by low energy UV light, TiO₂ is bactericidal and can degrade a wide range of organic contaminants including natural organic matter, a major membrane foulant. Furthermore, controlled release of Ag⁺ from Ag(0) nanoparticles can inhibit bacterial adhesion and growth (Yang *et al.* 2009; Zodrow *et al.*, 2009).

Nanotechnology could also help improve the energy efficiency of existing desalination technologies and develop novel, low energy consumption methods for desalination (Lind *et al.* 2009). Seawater is becoming an important source of water supply in many areas in the world. However, existing seawater desalination technologies are highly energy intensive. Utilization of nanomaterials (e.g., single wall carbon nanotubes) and biomaterials (e.g., aquaporins) has been explored to increase efficiency of membrane based desalination. Capacitive deionization (CDI) is a process that promises to provide a low-cost, energy-efficient technology for desalination. Removing salts by cation and anion electro-sorption in electrically conducting and porous electrodes, CDI avoids the high pressure required in RO and high temperature required in MSF, and provides high water recovery. The theoretically calculated as well as experimentally estimated energy consumption of CDI is more than an order of magnitude lower than RO. The current technology limitation lies in the low conductivity and low specific surface area of electrodes. We are developing novel electrodes with super high conductivity and surface area by employing vertically aligned carbon nanotubes, and evaluating their applicability for CDI of high salinity water.

Potential Risks to Human and Ecosystem Health

The nanotechnology revolution has a great potential to enhance not only water purification but also a wide variety of products, services, and industries. This promise, however, may be offset by the concern that some ENMs are toxic and may become a new class of hazardous pollutants that threaten public and ecosystem health if accidentally or incidentally released to the environment. Therefore, it is important to understand how released ENMs migrate, behave, and interact with living organisms and the abiotic components of the environment, and take proactive steps towards the long term goal of safer design and disposal of ENM-containing products (Klaine *et al.* 2008, Alvarez *et al.* 2009). Although the recognition of the environmental, health and safety issues of ENMs has been rising, research activities in this area are comparatively low, producing only about 5% of the total papers in environmental nanotechnology (Figure 1).

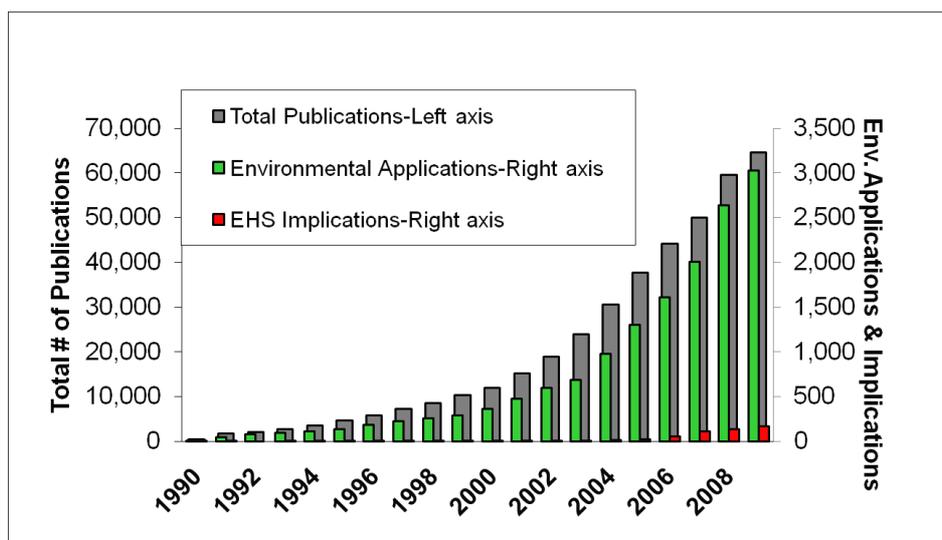


Figure 1. Comparison of the numbers of publications on environmental applications and implications (i.e., environmental health and safety, EHS) of nanotechnology (Source: ISI Web of Science, May 2010).

Whether ENMs could be designed to be “safe” and still display the reactivity or properties that make them useful is an outstanding question. Focusing on exposure control rather than suppressing intrinsic reactivity that contributes to toxicity might be appropriate in many cases. Thus, risk abatement options worthy of consideration include tailored coatings that reduce bioavailability or mobility, on-board packaging, and special disposal strategies. Yet, the modern chemical industry has demonstrated that some substances can be re-engineered to create safer, greener, and yet effective products. Encouraging examples include the substitution of branched alkylbenzene sulfonate surfactants, which caused excessive foaming in the environment, with biodegradable linear homologues, as well as the replacement of ozone-depleting chlorofluorocarbons by less harmful and less persistent hydrochlorofluorocarbons. Thus, it is important to discern the functionalities and physicochemical properties that make ENMs harmful, and determine which ecological receptors and ecosystem services might be at higher risks. Accordingly, priority research areas to inform the eco-responsible design and disposal of ENMs include:

1. Structure-activity relationships for ENMs in the environment. Modifying the physical and chemical properties of an ENM to affect its mobility, reactivity, bioavailability and toxicity.
2. Metrology, quantification and tracing ENMs. Analytical capabilities are needed to quantify ENMs in complex environmental and biological matrices (without alteration during separation and concentration) and determine the form that will reach receptors after they aggregate, dissolve, acquire/lose coatings, or undergo other transformations in the environment.
3. Bioavailability and sub-lethal effects. Standardized protocols are needed to investigate ENM cellular uptake mechanisms, trophic transfer and biomagnification potential (including discerning likely entry points into food webs) and sub-lethal effects that affect ecosystem services such as primary productivity, nutrient cycling, and waste degradation.
4. Predictive modeling of multimedia fate and transport. Computational models that predict the form and concentration of ENMs at the point of exposure will be important to identify the most susceptible compartments and ecological receptors and assess the associated risks.
5. Disposal scenarios and release dynamics. Immobilization and separation technologies need to be developed to retain ENMs in systems where their functions are desired. Meanwhile, sources and discharges into various compartments must be quantified (including ENM

leaching from products) as a first step to predict exposure and to evaluate the need for interception or remediation technologies.

Adopting principles of industrial ecology and pollution prevention should also be a high priority to steward ecologically-responsible nanotechnology (Table 2). Such measures can help the application of nanotechnology for sustainable water management while avoiding unintended impacts.

Table 2. The 12 Principles of Ecologically-Responsible Nanotechnology

1. Inherent rather than circumstantial (use raw materials and elements that are inherently non-hazardous if dissolved or otherwise released)
2. Prevention rather than treatment (containment, minimize exposure by choosing appropriate coatings, *design away hazardous functionalities or features without impacting useful functions*)
3. Design for separation and purification of nano construction wastes (take advantage of magnetic properties for separation / stabilizing coatings that can be intentionally removed after use to coagulated and precipitate MNMs / introduce surface properties to enable facile aggregation after environmental release)
4. Maximize mass, energy, space, and time efficiency (use multi-functional MNMs, quality > quantity, need > greed, enough > more, long-term > short-term)
5. “Out-pulled” rather than “input-pushed” through the use of energy and materials (drive manufacturing reactions to completion by removing products rather than increasing inputs of materials or energy, according to Le Châtelier’s principle).
6. Find opportunities for recycle, reuse or beneficial disposition (non toxic NPs that enhance nutrient or water retention and soil fertility?)
7. Target durability rather than immortality (avoid indefinite persistence)
8. Need rather than excess - don’t design for unnecessary capacity – avoid “one size fits all” (incorporate just what you need, avoid excess ENMs in commercial products)
9. Minimize material diversity to strive for material unification and promote disassembly + value retention (minimize variability and sources of a given ENM?)
10. Integrate local material and energy flows (holistic life cycle analysis perspective, look for interconnectivity, system of systems)
11. Design for commercial “afterlife” (enable recycling, remanufacturing and/or reuse opportunities, beneficial disposition)
12. Use renewable & readily available inputs through life cycle (minimize carbon, land use and water footprint)

Barriers for Implementation in Developing Countries

Insufficient technical capacity/knowledge needed to apply an advance technology might be an initial implementation barrier that could be relatively easy to overcome with an appropriate technology transfer program. This premise is supported by the widespread use of cell phones in developing nations.

Although the manufacturing costs of some ENMs (e.g., nano-magnetite) are predicted to be low in the near future, the current high cost of many ENMs is and may remain the main barrier for application in the water sector. Current costs of some ENMs are known (Table 3) but the cost normalized to the volume of water treated is unknown since their lifetime capacity (including recyclability) has rarely been tested to exhaustion. In addition, currently available cost information for many ENMs is based on small scale production and research grade ENMs. These complications preclude meaningful cost comparison with existing technologies. Despite the current high cost of nano-enabled products, their use in the water sector is likely to increase at the point of use/entry scale because of (1) highly valuable properties imparted at relatively low additive ratios; (2) rapid development of new

applications harnessing unique nano-scale properties; (3) decreasing trend in cost of nano-enabled products; and (4) save on capital investment for centralized infrastructure.

Table 3. Prices of Selected Nanomaterials of Interest to the Water Sector.

Zero Valent Iron, TiO₂ and Magnetite are currently available in (semi) bulk quantities. Others are more expensive research-grade materials.

Nanomaterial	Price (US\$/gram)
Nano Zero-Valent Iron	0.14
Nano TiO ₂	0.18
Nano Magnetite	0.44
Nano Iron-Oxide	1.20
Nano Silver	19.60
Fullerenes (C ₆₀)	330.00

Large-scale treatment plants can provide treated water at costs of as little as US \$0.1 to \$0.3 per 1,000 gallons of treated water over their life cycle. However, the initial capital cost of constructing the facilities is prohibitively large for developing countries (millions of dollars). Smaller point-of-use type treatment systems provide relative independence from extensive infrastructure and are much more reasonable in initial cost (on the order of US \$100) but may require much higher operating costs of as much as \$100 per 1,000 gallons treated for highly advanced point-of-use treatment systems. In order to be economically competitive in this cost range, current prices of nanomaterials would require that 1,000 gallons of water be treated by 200 g of titanium dioxide or 100 mg of fullerenes. As technology grows and prices of nanomaterials fall, this figure could become more realistic—especially in view of how many nanoparticles are in 1 gram of material.

Conclusions

ENMs have great potential to meet current and growing clean water demands throughout the world as the above-mentioned barriers are overcome. As the science and engineering of nanomaterials continue to grow, these improvements will likely come more and more rapidly. For instance the ability to use low cost, natural source materials and green manufacturing will reduce the environmental footprint and cost of nanomaterials. Additionally many of these technologies can take advantage of regeneration, reuse and recycling of ENMs to increase yield and further reduce cost. As the range and scope of pollution in water systems continue to increase we may see specialized treatment processes wherein nanotechnology can fill the gaps where conventional water treatment is either marginally effective or not feasible. Finally, efforts to control the release of ENMs into water systems will mitigate the environmental risk (and associated potential liabilities) until fate, transport and eventual impact of these materials are better understood.

Overall, it is important to capitalize on the leapfrogging opportunities offered by nanotechnology to improve and protect water quality. Furthermore, proactively assessing and mitigating potential environmental impacts of nanotechnology in the early stages of its development may result in better, safer products and less long-term liability for the industry. Indeed, due diligence is needed to ensure that nanotechnology evolves as a tool to improve material and social conditions without exceeding the ecological capabilities that support them.

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Title: Application of Nanotechnology in Food Safety Assessment:
Nano-Tracking Systems – Nanosensors.

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Introduction

Current and future concerns related to food safety and quality requires a multidisciplinary approach based on new generation of innovative technologies such as sensors/biosensors and tools to be used along the food chain. Applications include food pathogens and spoilage microorganisms, food contaminants such as toxins, pharmaceuticals, pesticides, heavy metals etc. The need for products control at different critical steps of the food chain such as of raw materials and food supply, improvement of food processing, monitoring of storage and logistics, and control of safety and quality of final products are essential to ensure food safety. Environmental pollutants and their impact on human's health have also increased the demands for monitoring the air, water and soil for contaminants that might impact on food safety. This needs a multidisciplinary know-how and the use of advanced technology for developing systems with clear innovative solutions to specific safety, quality and analytical requirements. The use of an integrated intelligence approach which will allow full interconnection and communication of multisensing systems is also advantages for food tractability. The use of nanotechnology inspired systems will be powerful in delivering and fulfilling these requirements.

Biosensors and affinity sensor devices have the ability to provide rapid, cost effective, specific and reliable quantitative and qualitative analysis in the food sector (Tothill 2001, 2003; Tothill & Turner, 2003). The increase in the number of analytes requiring monitoring and control with the increase in pressure to comply with legislations have stimulated considerable interest in developing multiarray sensors based on micro and nano systems as diagnostics and risk assessment tools. To date the technology is moving at a rapid pace with developments in novel biorecognition nanomaterials which can be used as the sensing receptors and advances in transducer technology at the nanoscale has resulted in more emerging products for multiplex analysis and nano-tracking systems which are feasible to fulfil the rapid monitoring and control need of the food chain. Micro and nano systems developed for logistic food surveillance by means of implementation of multisensing systems is also revolutionising food tracking. New advances in lab-on-a- chip technology, microarray and nanotechnology are also having a high impact on developing biosensors with new capabilities.

Advantages in the use of nanotechnology for food safety

Food producers are under pressure from crop disease and environmental conditions which threaten their profit margins. Also quality assurance along the food chain has made food safety and tractability a priority. Therefore, the use of lab-on -a-chip approach for the analysis of disease markers/ contaminants at the same time will be cost effective and highly beneficial for the food industry in ensuring the safety and quality of the food and also for risk assessment and management. Nanotechnology has the potential to improve food quality and safety significantly through the use of advanced sensors and tracking systems.

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The use of nanomaterials and structures such as semiconductors and conducting polymer nanowires, carbon nanotubes, silica nanoparticles and labels for biosensor applications is expanding rapidly and to date many comprehensive review articles have been published in this area (Katz and Willner 2004, Katz et al., 2004; Willner et al., 2007; Kerman et al., 2008). The application of nanotechnology in biosensors can range from the transducer device, the recognition ligand, the label and the running systems. Their application in sensor development has been due to the excellent advantages offered by these materials in miniturisation of the devices, signal enhancements and amplification of signal by the use of nanoparticles as labels. These can increase sensitivity of the final devices and also allow the fabrication of multiplex sensor systems such as high density protein arrays (Jain, 2004). The high surface to volume ratio offered by nanomaterials makes these devices very sensitive and can allow a single molecule detection which is very attractive in contaminant monitoring such as toxins. The use of nanowire transducers can also offer greater sensitivity in affinity sensors (Woolley et al., 2000; Wang et al., 2005).

The use of luminescent nanocrystals (Quantum dots) as molecular labels to replace fluorophores has created new applications for nanomaterials in labeling and visualisation. These nanocrystals can be attached as labels for antibodies and other molecules to detect different analytes at the same time (multiplex sensing). Quantum dots show distinct advantages over other markers due to their spectroscopic properties and narrow emission peaks and therefore their use in multiplexed analysis is increasing. Their high emission quantum yield result in improved signal / noise ratio and therefore decrease false readings (negative and positive).

The use of stripping voltammetry for detecting metal nanoparticles has been applied where these metals has been used as marker tags. Gold and silver nanoparticles can be used in these methods including different inorganic nanocrystals (e.g. ZnS, PbS, CdS) for analytes detection. The unique physical and chemical properties of nanoparticles such as colloidal gold can provide excellent application in a wide range of biosensing techniques (Rosi and Mirkin, 2005). Several products are available on the market such as Oxanica (UK) Quantum dots and MultiPlexBeads™ from Crystalplex Corp., USA. Nanoparticles can also be exploited in conductivity based sensors where they can induce a change in the signal upon the attachment of the nanoparticles- antibody tagged with the captured antigen on the sensor surface. Gold nanoparticles are easy to functionalise and are used for antibody immobilisation, making this process more reducible.

The development of micro/nanosensor devices for toxins analysis is increasing due to their extremely attractive characteristics for this application. Their novel electron transport properties make them highly sensitive for low levels detection (Wang, 2005, Logrieco et al., 2005). The multiplex analysis capability is also very attractive for multi biomarker analysis. The development of methods of near real time pathogen and disease detection and location using micro (MEMS) and nano multisensory systems with new chip designs and capabilities will allow analysis to be taking place before the product reach the consumer. Multi toxins detection (e.g Mycotoxins) in foods can be conducted using single miro/ nanoelectrode array chip with high sensitivity and rapid analysis time. Therefore, the application of lab-on-a-chip using semiconductor fabrication techniques is expanding in all areas of analysis due to the advantages of using small samples to analyse several microorganisms/toxins i.e offer high throughput analysis. Productivity would increase through diagnosing disease early, so that

action can be taken early to control the problem. The use of micro/nanoarrays for analysis applications in foods can produce highly sensitive sensors.

At Cranfield we are developing novel nanomaterials and also using commercially available nanoparticles such as gold and silica and micro/nano arrays as transducers for toxins, bacteria and other biomarkers analysis to enhance the signal achieved on the surface of the electrochemical sensor, QCM and SPR sensor systems and also for multiplex analysis for several biomarkers (Tothill et al., 2001; Tothill, 2009; Parker et al., 2009; Tothill, 2010; Uludag & Tothill, 2010)

New legislations introduced both in the EU and the USA indicate that tracing food from the field to the factory and then to the supermarket shelf is a legal obligation. The use of radio frequency identification (RFID) technology has been implemented by retailers to track the food and automate its traceability. New developments in nanomaterials and nanosensors/nanosystems have the ability to produce new and advanced traceability tools. Nanoscale Identity Preservation (IP) is a technique that could lead to the continuous tracking and recording of agricultural batches and the conditions they are being exposed to. Sensors could then be linked to recording and tracking devices using wireless and blue tooth technology. Nanosensors embedded in food packages can then be used as electronic barcodes which allow traceability and tracking combined with food spoilage markers and deterioration monitoring, increasing the capability of current technologies.

Challenges facing technology development

The application of nanotechnology in the development of nanodevices for sensing and tracking face many challenges. The technology is still developing and therefore many issues and problems still need to be resolved regarding producing viable systems suitable as commercial products. Also the variety of biological complexity of molecular structures and the wide range of concentrations need to be detected, coupled with the complexity of the food matrices are some of the bio-analytical challenges facing the application of nanodevices for food analysis. The stability of some nanomaterials such as quantum dots needs improving, reduce aggregation in use conditions and also reduce cost as they are expensive to date. Problems associated with sample treatment, delivery to the nanosensor devices still require extensive investigation to develop a better microfluidic systems and informatics tools for signal output.

Currently a lot of work is being carried out with huge investments from industry and governments to develop nanosensors and nanosystems targeting improved detection (sensitivity and selectivity), multiplexing analysis (analysing several analytes at the same time), rapid out (short analysis time), on-site in field analysis (portable devices), and cost effective (low cost compared to lab based analysis). These are big challenges which will require few years of research and developments before they can be materialised.

Key concerns regarding technology implementation

Concerns about the use of nanotechnology in this particular application is limited due to low exposure of food to the toxicity risks associated with nanomaterials, since food samples are usually disposed of after analysis. Therefore the risk is only reduced to the wider issue of toxicity risks for humans and the environment after the disposal of these devices and materials. In nano-tracking, loss of privacy may be of concern as nano surveillance will be

able to track each step in the food chain. This may have impact on the food producer, the manufacturer and also the consumer.

We should however, take the signs associated with the toxicity of nanoparticles very seriously and ensure and control their safe disposal, especially the potential risks posed by engineered nanoparticles, until further studies prove otherwise.

Conclusion

The biosensor field is moving forward at a rapid pace with developments and innovation taking place at all levels including the sensing receptor, the transducer and the accompanying electronics and software. As we progress from single analyte testing to multianalyte analysis, miniaturisation and nanotechnology playing a big part in producing highly sensitive and cost effective devices.

There are very attractive technologies being developed for food safety and tractability which can be applied at all levels whether it is in the farm or the factory and can be operated for on-site analysis by unskilled personnel. Trends to further develop and produce chip-based micro/nanoarrays for multi analyte analysis will continue and this will have significant impact on risk assessment testing. The introduction of the diverse array of nanomaterials such as gold and silver nanoparticles and other metal oxides such as quantum dots for diagnostics application will enhance and elevate the capability of the biosensor technology. Also the advances in silicon fabrication technologies is producing more defined and reproducible array devices and that will add further improvement on the final sensing devices. This however, needs to be combined with developments in sampling acquisition and sample handling procedures.

Bio- and affinity sensors have the potential to provide rapid and specific sensing for food quality assurance. Analysing contaminants (chemical and microbiological) at the required legislative limit require highly sensitive devices that allow rapid diagnosis. Also it is advantages for these techniques to be portable since a large number of analyses could benefit from on-site testing for risks assessment and management. Therefore, there is a need for simple and sensitive diagnostics methods that can detect multiple analytes which exist at low concentrations in different foods and feeds matrixes. However, biosensor devices need to be further developed to face these challenges such as multiplex analysis where arrays of sensors need to be developed at the same chip. Innovation in nanotechnology to include analysis software and micro/nanofluidics can aid in the development of such devices. Applying nanomaterials in the development of the sensors will make these devices highly sensitive and more applicable for lab-on-a chip diagnosis. Early and sensitive detection will aid in eliminating contaminants from interrupting the food chain and preventing ill health and protecting life. Therefore these rapid technologies need to be developed further using appropriate funding to move the technology from research to commercial products.

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Title: Applications of Nanotechnology in Agrochemical Formulation: Perspectives, Challenges and Strategies

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Introduction

Nanotechnology offers a new way for transforming formulation of agrochemicals, such as bioactive compounds, fertilizer, growth regulator, herbicide, and pesticide, etc. Nanostructured formulation could release their active ingredients in responding to environmental triggers and biological demands more precisely through targeted delivery or controlled release mechanisms. Such nanobased agrochemical products hold great potential to benefit environment in terms of reducing overall chemical usage that may cause pollution in the water system and contamination in crops and food products. Therefore, nanotechnology has become a new impetus for overall sustainable agriculture, especially in developing countries. Here our focus is placed on the challenges and the overcoming strategies regarding development of nanopesticides and nanofertilizers.

The R&D Status and Prospects of Nanopesticide Formulation

The loss and decomposition rate of active ingredients in conventional pesticides during the application process is typically up to 90%. The actual utilization of biological targets is only less than $1/10^4$. Using nanoscale and nanostructured materials as the delivery carriers and vector systems might bring about beneficial changes in properties and behaviour of pesticide formulation, such as solubility, dispersion, stability, and targeting delivery efficiency, and controlled release of active ingredients. Furthermore, it might also not only significantly improve the bioavailability and the duration of drug efficacy, but also reduce the residual contamination of food and environment. There are many advantages for nanopesticides as summarized in Table 1.

Table 1. Opportunities for Nanotechnology in Transforming Pesticide Formulation

<i>Desirable Properties</i>	<i>Examples of Nanopesticides-Enabled Technologies</i>
Targeted delivery and controlled release	Controlled release speed of active ingredients to maintain continuously and dynamically least effective concentration for killing pests and pathogens in environmental media and biosystems
Solubility and dispersion for insoluble ingredients	Aqueous colloid and nanosuspension of pesticides substitute EC Products aimed for avoiding the pollution of organic solvents
Chemical stability	Nanoencapsulated biopesticides, such as antibiotics, growth stimulants and bioactive agents might display excellent properties in stability, bioavailability and persistence of the bioactive chemicals by restricting photodegradation.
High bioavailability	Reduced use of pesticides in crop protection
Longer duration of persistence	Reduced application of pesticide and related labour cost
Controlled release and delivery modes	Formulated high-efficacy delivery and controlled release system for pesticide encapsulated in nanocapsules and mesoporous

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	nanoparticles
Lower toxic to non-target wildlife	Protected biodiversity in agricultural ecosystem
Lower residual pollution	Reduced food residues and non-point source pollution due to the minimum pesticide loss

Currently, most researches on nanopesticides in China are primarily focused on the improvement of environment friendly properties to overcome environmental and food safety problems due to the application of pesticides in crops production. A multi-disciplinary research team led by Chinese Academy of Agricultural Sciences is investigating the targeting delivery and controlled release of agricultural bio-drugs, including bio-pesticides, veterinary medicines and vaccines. This research is supported by the National High-Tech R&D Program, (863 Program), Grant No. 2006AA10A203, and Grant No. 2007AA021808. Some significant progresses have been achieved in the area of nanoencapsulation and nanostructured carriers as controlled release and delivery systems for agro-antibiotics, such as avermectin, ivermectin, and validamycin, etc. Such achievements might facilitate the larger scale uses of bio-pesticides in crop production. The nanoemulsion of some fat-soluble pesticides has been developed successfully. Mesoporous particles, such as nanoclay, activated carbon and porous hollow silica were also verified to be suitable for the controlled release and delivery carrier systems for the water-soluble and fat-dispersible pesticides which have a high drug-loading capacity and multistage release pattern. However, there are some technical obstacles that need to be addressed in the near future (Table 2).

Table 2. Priority Issues in R&D of Nanopesticides

<i>Technical Obstacles</i>	<i>Priority Issues of Nanopesticides-Enabled Technologies</i>
Delivery carrier systems formulated by mesoporous material or molecular sieve	To control releasing speed of active ingredients in response to environmental and biological triggers and reduce food residues and environmental pollution caused by loss of pesticide compounds
Nanoencapsulation in the form of nanocapsules, micelles, liposomes	To stabilize chemical properties and bioactivity of pesticides by using nanoencapsulation to protect active ingredients sensitive to light, such as bio-based compounds, from photo-degradation
Targeting compound modification	To increase targeting delivery efficiency through improving behaviors of wetting, spreading and absorbing of drug droplets on surface of leaves, and penetration and uptake of active compounds into the infected organs, insects or pathogens
Nanosized processing	To render higher solubility and dispersion for insoluble or fat-dispersible compounds in aqueous solution
Inclusion complexes	To control release and protect drug molecules by absorbing pesticides with nanostructured polymers or mesoporous materials, such as hollow fiber, porous silica and activated carbon
Granulation coated with nanostructured-polymers	To create slow/controlled release formulation of insecticides and fungicides to control soil infection diseases and soil pests
Nanoemulsion	To increase solubility and dispersion for fat-soluble drugs in aqueous solution by self-emulsifying delivery system
EC alternative products with aqueous colloid dispersion system	To develop environment friendly formulation without toxic organic solvents for fat-soluble compounds, which is easier to be dissolved and dispersed in aqueous solution

Based on the current researches progress on nanopesticides in China, it is our expectation that the following R&D objectives will be realized in the next 5-10 years.

- Slow/controlled release formulation of insecticides and fungicides might widely used for the control of soil infection diseases and soil pests, so as to reduce chemical residues and pollutants in soil and foods caused by leaching and leaking of toxic ingredients in pesticides.
- Aqueous colloid dispersion and nanosuspension of pesticides would gradually substitute EC products to avoid the pollution of organic solvents.
- Nanoencapsulated bio-pesticides, such as antibiotics, growth stimulants and bioactive agents will gradually replace their conventional equivalents because of the excellent properties in stability, bioavailability and persistence of the bioactive chemicals.

The R&D Status and Prospects of Nanofertilizer Formulation

The yield-increasing effect of fertilizers is subjected to the law of diminishing marginal returns. With the increase in the amount of fertilizer per unit area, its input-output efficiency and nutrients absorbing rate will reduce continually. On the contrary, Soil nutrients loss will increasingly exacerbate water body and non-point source pollution. Currently, the average utilization rate of chemical fertilizer in China is typically less than 30%. In other words, more than 70% fertilizer nutrients are lost through some processes in the soil such as leaching, leaking, bio-transformation and soil fixation. Thus, the development of precisely controlled release fertilizers based on nanotechnology has become critically important for promoting the development of environment friendly and sustainable agriculture. Application of nanotechnology has demonstrated great prospects in the breakthrough of technical bottleneck of slow/controlled release fertilizer using Nanoscale or nanostructured materials as fertilizer carriers or controlled-release vectors for constructing of so-called “smart fertilizer.” The development and application of nanofertilizers will demonstrate some advantages over their conventional counterparts such as: (1) Increased efficiency and quality of nutrient supply with a higher uptake rate; (2) Releasing fertilizer nutrients at a dynamically controlled rate throughout the season so that plants are able to take up most of the fertilizers without loss by leaching; (3) Substantial reduction in pollution of soil, water reservoirs and food products; (4) Mitigation of soil compaction and quality deterioration; (5) Reduction of plant toxicity and stress from high local concentrations of salts in the soil; (6) Reduction of fertilization costs by reduced fertilizer dose and application frequency ; (7) Increased crop production by the improved nutrient status; and (8) Improved storage and handling properties of fertilizer materials . The R&D advances on nanostructured formulation of fertilizers are summarized in Table 3.

Table 3. Recent R&D Objective and Progress of Nanofertilizers

<i>Desirable Properties</i>	<i>Examples of Nanofertilizers-Enabled Technologies</i>
Controlled release formulation	So-called smart fertilizers might become reality through transformed formulation of conventional products using nanotechnology. The nanostructured formulation might permit fertilizer intelligently control the release speed of nutrients to match the uptake pattern of crop
Solubility and dispersion for mineral micronutrients	Nanosized formulation of mineral micronutrients may improve solubility and dispersion of insoluble nutrients in soil, reduce soil absorption and fixation and increase the bio-availability
Nutrient uptake efficiency	Nanostructured formulation might increase fertilizer efficiency and uptake ratio of the soil nutrients in crop production, and save fertilizer resource

Controlled release modes	Both release rate and release pattern of nutrients for water-soluble fertilizers might be precisely controlled through encapsulation in envelope forms of semi-permeable membranes coated by resin-polymer, waxes and sulphur
Effective duration of nutrient release	Nanostructured formulation can extend effective duration of nutrient supply of fertilizers into soil
Loss rate of fertilizer nutrients	Nanostructured formulation can reduce loss rate of fertilizer nutrients into soil by leaching and/or leaking

In China, the development of nanobased slow or controlled-release fertilizers have been actively implemented since the beginning of this century and supported by the National High-Tech R&D Program. Significant progress has been made especially on film-coating urea and granular compound fertilizers. Some nanobased agrochemicals have been commercialized. The solubility and dispersion of insoluble mineral micronutrients and phosphate fertilizers have been significantly improved by nanosized or nanostructured processing. However, there are still some major technical obstacles and priority issues that need to be addressed and overcome in the near future (Table 4).

Table 4. Key Technical Obstacles and Priority Issues in R&D of Nanofertilizers

<i>Technical Obstacles</i>	<i>Priority Issues of Nanopesticides-Enabled Technologies</i>
Film coated granulation with nanopolymers	To create granular compound fertilizers with smart controlled release modes in order to reduce fertilizer loss occurring on the process of leaching, bio-degradation, and migration of fertilizer nutrients in soil, and inhibit non-point source pollution and water body eutrophication
Nanosized preparation of insoluble nutrients	To improve solubility and dispersion of mineral micronutrients and phosphate fertilizers aimed to increase absorption efficiency by inhibiting soil absorption and re-mineralization, and immobility
Compound absorption with mesoporous materials, such as nanoclay and porous minerals	To develop multi-compound fertilizer with property of precisely controlled release in order to improve fertilizer nutrients efficiency and synergistic effect
Sulphur or paraffin coated Encapsulation	To develop environment-friendly and controlled release formulation for soluble nitrogen fertilizer encapsulated or coated by sulphur or paraffin wax, such as sulfur coated urea

With the current development, by the next decade, nanostructured formulation of controlled release fertilizers will become matured technology that will enable wider application in large-scale crop production for developing countries. The applications may primarily include following aspects: (1) to promote environment friendly and green crop production, especially the production of paddy and horticultural crops, inhibiting soil non-point pollution and water body utrophication; (2) to increase input-output efficiency in crop production through the improvement of fertilizer efficiency, and promote development of sustainable agriculture; (3) to overcome resource shortage of mineral micronutrients and phosphate fertilizers by the application of higher efficiency nanostructured products.

Potential Risks and Barriers in the Development of Nanoagrochemicals

Nanoagrochemicals have a great potential to enhance their input-output efficiency, ecological and environmental benefits. However, these advantages might be offset by some potential risks of human health and ecological disasters. The general concern is that some nanoparticles or nanostructured materials may flow into the environmental systems and food from nanoagrochemicals or agronanochemicals may be toxic, which may become a new class of pollutant resources that threaten human health and ecosystem balance. Therefore, more researches are needed on safety and risk assessments of nanoagrochemicals. The results on studies of toxicology and safety evaluation of nanobased medicines may be referred to agrochemicals, as they used some similar technical lines and ideas. Also, in the development and production of nanoagrochemicals, nanostructured materials with larger size particles might be more safe and effective than solid nanoparticle materials used for delivery carrier and control release media in transforming formulation of fertilizers and pesticides.

Although nanoagrochemicals dominated by fertilizers and pesticides worldwide appeared good prospects in promoting environment friendly and sustainable agriculture, the high cost of nanoagrochemicals, which is generally 3 to 4 times more expensive than the conventional products, forms a huge barrier for their large scale application in crop production for developing countries. However, as the expansion of production scale and application scope, market price would be reduced sharply. Increased cost by slightly higher unit price of the product could be offset by saving per unit area as their more than two times higher efficiency compared to conventional equivalents. Henceforth, the application of nanoagrochemicals in crop production should be treated as a novel innovative strategic high-technology or focused on ecological and environmental benefits to implement financial support or subsidies. In general, the use of nanoagrochemicals starts to evolve as a promising direction offering an excellent means to improve management of fertilization and crop protection by reducing significantly environmental threats while maintaining high crop yields and good quality.

Strategies for Promoting Applications of Nanoagrochemicals in Developing Countries

In order to facilitate applications of nanoagrochemical technologies in developing countries, the following strategies and management policies should be implemented:

1. **Strengthen R&D activities and innovation platform:** State/provincial or central government agencies should have clear R&D priorities suitable for the state/province or the region, and actively engage in universities and research institutions in the debate of R&D priorities, then strategically increase priority R&D budget for multi-disciplinary collaborative research activities, therefore to strengthen research infrastructure and platform establishment.
2. **Improve extension system and support policy:** An integrated extension system should be in place in order to promote the integration of R&D activities with industry and economic development, strengthen the management of the processes of technical extension and products production. Support policies including financial support measures should be established and actively enforced.
3. **Enhance product quality assurance and supervision and market management:** This is a policy issue. It is absolutely necessary to establish specific product standards, the validation and registration rules for nanoagrochemicals should be actively enforced.

Concluding remarks

Clearly, nanofertilizers and nanopesticides have many advantages over their conventional equivalents such as high efficiency, environment friendliness, high-targeting delivery and

smart controlled release. Due to their technological advancement, large scale applications of nanofertilizers and nanopesticides in crop production have just become possible. As a most promising and attractive field of nanotechnology application in agriculture, these novel agrochemical products will provide multiple benefits such as reduced use of chemicals and subsequently reduced water pollution and food product residual contamination, efficient use of agricultural resources, increased soil and environmental qualities. As a novel high-tech for agriculture, nanotechnology will no doubt help ensure food security, development of environment friendly and sustainable agriculture in developing countries and regions. Central and/or state/provincial government agencies should and must have clear R&D priorities and governing policies in place, strategically invest in such high tech areas to strengthen the construction of research infrastructure and platform and product development, and applications of such nanotechnology products through integrated extension system.

Title: Nanotechnology in agriculture: increasing pressure on small scale farmers

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Key issues

Global agriculture and food systems are under acute stress

Industrial scale chemical-intensive agriculture has resulted in biodiversity loss, toxic pollution of soils and waterways, salinity, erosion, desertification and declining soil fertility (FAO 2007). Nearly a billion people face extreme food insecurity.

Empowering small scale farmers to meet their own food needs is essential

Around 75% of the world's hungry people live in rural areas in poor countries (FAO 2006). If rural communities can meet more of their own food needs via local production, they will be less vulnerable to global price and supply fluctuations. La Via Campesina has argued that: "Small-scale family farming is a protection against hunger" (La Via Campesina 2008). The four year International Assessment of Agricultural Science and Technology for Development emphasised that to redress rural poverty and hunger, small scale farmers must be empowered to meet their own food needs (IAASTD 2008).

Nanotechnology is likely to intensify economic pressures on small farmers

Nanotechnology proponents (IFRI 2008) and academics keen to promote the Millennium Development Goals (Salamanca-Buentello et al. 2005) have suggested that nanotechnology's use in agriculture will deliver environmental sustainability and eradicate hunger. Friends of the Earth Australia suggests that by entrenching dependence on industrialised, export-oriented agricultural systems and the chemical and technology 'treadmills' that underpin it, nanotechnology is more likely to intensify pressures on small farmers.

Nanotechnology has transformative potential – not just 'good' or 'bad'

Although our analysis is that on the whole nanotechnology is likely to intensify pressures on small farmers, we recognise that agricultural nanotechnologies do not present dichotomous 'advantages' and 'disadvantages'. In many instances the same technology poses advantages and disadvantages to different actors, as well as broader challenges. Agricultural nanotechnologies could also have profoundly transformative effects. They could radically alter the nature of farming systems, rural communities, agricultural biodiversity and food production (Scrinis and Lyons 2007).

High tech nano-agriculture aims for more uniform, more efficient, less labour intensive systems: this poses diverse social and economic challenges

The vision of many proponents of agricultural nanotechnologies is one of precise production: more uniform, more efficient, less labour intensive, more remotely managed, atomically 'improved' crops whose high productivity is made possible by entwined nano-surveillance and 'smart' farm management systems, nano-modified seeds and specialist interactive chemical treatments (USDA 2003). This could accelerate land consolidation, agribusiness

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growth at the expense of small farms, increase monoculture production and result in further loss of agricultural biodiversity.

Agricultural nanotechnologies will have comparatively high capital costs, but deliver greater efficiencies in operation. This could deliver a near-term competitive advantage to larger or wealthy farmers who could afford them, while being inaccessible to smaller, poorer farmers. 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 and seed companies, food processors and food retailers to the detriment of small operators (ETC Group 2004; Scrinis and Lyons 2007).

Agricultural nanotechnologies pose significant intellectual property challenges. ‘Smart’ surveillance and nano-farm management systems could embed traditional farming knowledge in proprietary technologies to which access would require purchase. This could result in loss of traditional farming knowledge, entrenching reliance of farmers on technologies that they do not control and are unlikely to have the specialist knowledge or equipment to maintain. This will undermine the self-reliance of small farmers.

Remote or automated farm management systems may be vulnerable to technology malfunction, interference, or breakdown. It is conceivable that a given manufacturer or owner of ‘software’ could at some future point be unable to service agricultural nanotechnologies on which farm management comes to depend.

Each wave of technological innovation has created further efficiencies and consequent waves of job-shedding in agricultural industries (Hisano and Altoé 2008). At this early stage of nanotechnology’s development there is no data specific to it. However we do know that the development of highly efficient, automated farm management systems is a key aim of nanotechnology proponents. Reducing on-farm labour is often touted as a positive. However further reduction in rural employment could promote increased rural-urban migration. The declining viability of small scale farms and falling jobs in the rural sector has already caused ‘distress’ migration of farmers to urban areas in many Southern countries, resulting in a rapid increase in urban poverty (FAO 2002).

Nanotechnology also poses health and environmental challenges

Combined nano-surveillance systems and ‘smart’ automated farm management could potentially reduce the need for on-farm inputs (eg fertilisers, pesticides, water) by targeting applications to more precisely identified needs. This could lead to water savings. However although such systems may reduce the quantity of agro-chemicals used, they entrench dependence on a chemical-intensive model of agriculture at a time when there is growing interest in agro-ecological and organic farming.

Proponents of nanotechnology also suggest that because nano-agrochemicals are formulated for increased potency, they will be used in smaller quantities, thereby delivering environmental savings (Joseph and Morrison 2006; USDA 2003). However, due to the increased potency of nano-agrochemicals, this may not reduce their toxicological burden. The Woodrow Wilson International Center for Scholars has suggested that the toxicological impact of 58,000 tonnes of manufactured nanomaterials might be the equivalent of 5 million or even 50 billion tonnes of conventional materials (Maynard 2006).

Nano-chemicals and nano-modified seeds may introduce novel environmental and health toxicity. There is preliminary evidence of serious health and environment risks associated with manufactured nanomaterials (RCEP 2008; SCENIHR 2009) and acknowledgement by leading researchers that the extent of uncertainty is such that reliable risk assessment systems do not yet exist (Hansen 2009; Oberdörster et al. 2007). The European Food Safety Authority (EFSA 2009) has stressed that scientists do not yet have the capacity to design a risk assessment process in which we can have confidence, and which is capable of guaranteeing safety:

"Although, case-by-case evaluation of specific ENMs [engineered nanomaterials] may be currently possible, the Scientific Committee wishes to emphasise that the risk assessment processes are still under development with respect to characterisation and analysis of ENMs in food and feed, optimisation of toxicity testing methods for ENMs and interpretation of the resulting data. Under these circumstances, any individual risk assessment is likely to be subject to a high degree of uncertainty. This situation will remain so until more data on and experience with testing of ENMs become available" (EFSA 2009, p2-39).

Leading nanotoxicologists have cautioned that validated nano-specific risk assessment methodologies may take many years to develop (Maynard et al. 2006). The need to adopt the precautionary principle to manage the serious but uncertain risks associated with nanotechnology has been recognised explicitly by governments from 5 continents. At the 2008 International Forum on Chemical Safety 71 governments, 12 international organisations and 39 NGOs recommended "applying the precautionary principle as one of the general principles of [nanotechnology] risk management" (IFCS, 2008).

The use of nanotechnology in agriculture is of particular concern as it involves the intentional release of agricultural pesticides, plant growth treatments and modified seeds into the environment. Very few studies have examined the ecological effects of nanomaterials and their behaviour in the environment remains poorly understood. For example it remains unknown whether or not nanomaterials will accumulate along the food chain (Boxhall et al. 2007). In its seminal report on nanotechnology, the United Kingdom's Royal Society and Royal Academy of Engineering recommended that the release of nanomaterials into the environment should be avoided as far as possible (Recommendation 4, RS/RAE 2004).

Potential solutions to address challenges identified

Firstly, given the serious nature of the crisis gripping agriculture, we must not assume that certain technologies offer unproblematic solutions. We must clarify the goals of agricultural policy and development before we can evaluate the extent to which nanotechnology or other technologies can offer solutions, or to which they may simply exacerbate existing problems. Friends of the Earth Australia (FOEA) suggests that the key goals of agricultural policy should be to reduce hunger, to strengthen the self-reliance of small farmers, to improve the ecological sustainability of food production, to maintain agricultural biodiversity and to prepare for a deepening of existing stresses associated with climate change and population growth.

Secondly, we must evaluate the extent to which technological and non-technological options are able to contribute to the goals of agriculture and development. We suggest that nanotechnology, along with other technology and non-technology agricultural options, should be evaluated in relation to its likely contribution to meet the needs of small farmers while

bolstering, rather than diminishing, their own sufficiency and capacity for self-reliance. In our assessment, while it offers apparent advantages in some aspects, nanotechnology is likely to add to the pressures faced by small farmers, thereby posing a net cost.

It is always worthwhile to query to what extent negative aspects can be overcome through policy initiatives. However FOEA is concerned that there is no ready solution to nanotechnology's probable intensification of pressures on small farmers as the problem exists at a number of levels:

Economic/ commercial pressures

Intellectual property: Nanotechnology research is expensive and to a large extent, public and private sector sponsors will be looking to recoup research outlays through product commercialisation. A potential solution is to support substantive intellectual property reform that would result in delivery and future maintenance of free agricultural nanotechnologies. However this appears practically improbable, especially in the long term. Further, short-term 'honeymoon' deals (eg where agricultural nanotechnologies may be offered free or at a reduced cost for some initial period of time) would simply delay the problem, while promoting uptake of and reliance on nanotechnologies now

Entrenched reliance of farmers on corporate technologies: Due to the elite nature of nanotechnology research, its utilisation as a 'black box' technology is inescapable. To the extent that nanotechnology 'smart' farm management systems, 'smart' agrochemicals and surveillance systems did replace on-farm labour, these would also commodify existing farm management knowledge and embed it in these new proprietary systems.

Systemic tendencies that increase commercial pressures on small farmers: It is likely that nanotechnology would increase scales of production, uniformity of produce, growth of monoculture crops, consolidation of farms into larger units and more production for export markets. It is unlikely that nanotechnology would result in greater agricultural biodiversity, greater diversity of small farms, greater empowerment of small farmers or more production for local markets. There is no solution to this – nanotechnology has inherent tendencies to centralisation

Social pressures:

Social/ economic disadvantage: Many social pressures overlap with the economic pressures identified above. This is especially acute in relation to the potential loss of rural/ on farm employment, the potential further consolidation of small farms into larger farms and the likely social upheaval that would result as rural migration intensified. The potential commodification/ loss of farming knowledge is also a serious social and cultural issue. As discussed, there are no ready solutions here.

Right to choose: Measures can and should be implemented to enable small farmers and farming representative bodies to take part in decision making about nanotechnology policy, research funding allocation and government support for industry development. This requires not only labelling, education and information to enable individual farmers to make decisions about their own use of nanotechnologies, but also explicit recognition of the right of local farmers and farming communities to participate in decision making about agricultural policies

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that affect them, including the adoption or rejection of elite technologies, and the extent to which public research funding should be invested in this research and industry support

Government policy – ensuring public interest management of nanotechnology

Assessing opportunity costs of nanotechnology investment: FOEA is concerned about the opportunity cost of investing in nanotechnology research, development and commercialisation in preference to more sustainable and localised farming models, or in social and economic initiatives to better support small-scale farmers. A solution is for governments to conduct an assessment of the capacity of nanotechnology to meet key social and environmental objectives, compared to other technology and non-technology options. This should inform the allocation of public funding for research and industry support

Prioritising public interest science: public funding should be targeted to research and development that has a demonstrable public interest benefit, where the needs of small farmers are prioritised over the competitiveness of agribusiness at large

Environment and health impacts associated with nanotechnology in agriculture:
Some environmental pressures associated with agricultural nanotechnologies do not have a ready solution (eg probable acceleration of loss of agricultural biodiversity associated with increasing tendencies to larger farms, more uniform produce)
The novel environment and health risks associated with the use of nano-formulated agrochemicals, seeds and other agricultural products should be regulated according to the precautionary principle. Nano-forms of bulk chemicals should be treated as new chemicals and subject to new, nano-specific safety assessment. The onus should be on the product proponent to demonstrate safety

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Title: Nanoparticle-based drug delivery for hormones: new tools for pharmacological control of the estrous cycle in ruminants.

Name: Ed Hoffmann Madureira¹, Lúcio Cardozo Filho

Introduction

Nanotechnology is a relatively new area of science and several authors have suggested its application in various fields of animal production and health. In order to enrich the discussions, several publications such as EMERICH; THANOS (2006), NARDUCCI (2007), SCOTT (2007) and KUZMA (2010) may be consulted.

The management of animals can be relatively difficult when there's a need to administer many different medications. Therefore, there's always been a need for formulations that allow a sustained release of the active ingredients, specially antimicrobials, anti-inflammatories and hormones. This can be achieved with the application of nanotechnology.

Another field of use would be in vaccines where it could improve the immune response through the continuous stimulus of the immune system.

The already available so-called long-acting drugs do not have adequate pharmacokinetics, which exposes the animals to excessive concentrations of the active ingredient in the beginning of the treatment and many times, concentrations below the therapeutic dose by the end of the treatment.

As a rule, drugs considered as long-acting have very aggressive vehicles and employ inadequate pH ranges for intramuscular administration, leading to local lesions at injection sites, responsible for an inferior meat quality.

Key issues

Brazil is one of the largest producers and exporters of beef in the world and the cattle herd consists of approximately 200 million heads of cattle. Of these, about 70 to 80 million are females of reproductive age. There are many challenges to improve reproductive performance and still get a genetic improvement in the breeding herd. For this, Artificial Insemination is an essential tool.

Our area of expertise is the pharmacological control of the estrous cycle, with the goal of synchronization of ovulation in cows in order to enable Fixed-Time Artificial Insemination (FTAI). The use of FTAI has provided a significant increase in the production of beef and dairy cattle and it has been widely used in producing countries. In Brazil, it has been estimated more than 3 million FTAI in the last year.

Among the main limitations for FTAI, in which nanotechnology could be useful are: a) the animals must be managed 3 to 4 times until the time for artificial insemination, b) the products used are based on progesterone dispersion in a silicone matrix and, after its use, remains a considerable amount of hormone residue in the devices that have to be discarded, c) the release of progesterone from these devices, although acceptable, is irregular, d) the devices must be removed from the vaginal cavity at the end of the treatment period, which leads to one more animal handling.

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Challenges identified

To circumvent the limitations listed above, the main challenges are:

a) improve the bioavailability of progesterone, providing better control of the dose, b) develop more appropriate formulations for different animal categories – heifers, dairy and beef cows have different progesterone requirements, c) formulate new veterinary medications in which progesterone content runs out by the end of the treatment to avoid the need for its removal, handling and disposal after use.

Strategies to overcome the challenges

In order to develop new formulations, it's necessary a production of nanoparticles with polymers that have certain properties such as biodegradability and biocompatibility, select among the various techniques such as emulsification/solvent evaporation, emulsification/solvent diffusion, miniemulsification/ evaporation or solvent extraction and nanoprecipitation (or displacement of solvent) using processes based on supercritical fluid for the production of nanoparticles prepared from preformed polymers, evaluation of the type and concentration of surfactant in the formation of miniemulsions and nanoparticles of biopolymers, establish an ideal loading and releasing efficiency rate for each individual drug allowing large scale production and economically feasible for its desired application.

As strategies to overcome these challenges there needs to be a modification of polymeric materials by manipulating the biocompatibility and biodegradability of the synthetic nanoparticles polymers, use of hybrid natural/synthetic polymer that offers new possibilities, since it is expected that the release should also be influenced by the composition of particles and how these polymers interact with each other and with the drug, and the introduction of stabilization techniques combining new surfactants and physical processes such as ultrasound.

Once a series of materials and methods is available for the production of nanoparticles, it becomes essential the need for the development and validation of analytical techniques for testing of nano-structured formulations, both “in vitro” and “in vivo”. For “in vitro” tests, there is a need for standardization of delivery systems, adjustment of the formulations, stability and quality control tests.

The “in vivo” tests should also be emphasized, because if the formulations can provide improvements in the bioavailability of active ingredients and reduce meat and milk residue, then there's a need for analytical techniques sensitive enough to differentiate the traditional formulations from the nano-structured. Validation of techniques for measurement by mass spectrometry (LC / MS / MS) in different matrices such as blood, meat, milk, fat and other specific organs, becomes imperative.

Conclusion

In the area of animal reproduction, there is enough information on the physiology of the endocrine system and great interest for veterinary medications, which can be used to improve the reproductive performance of beef and dairy herds. In parallel, there is enough information on material engineering, production techniques and characterization of nanoparticles as well as “in vitro” and “in vivo” testing of nanostructured formulations.

It can be concluded that basic research already holds significant expertise in nanotechnology to generate in the short term, major technological products. This is happening in a peculiar economic moment in which there is increasing demand for effective products

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that can contribute to sustainable livestock development and at the same time meeting the requirements of animal welfare, consumer and environment safety.

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Title: General insight on regulatory framework and nanotechnologies**Name:** Alan Reilly¹**Introduction**

The application of nanotechnology in the food and feed industry offers many potential benefits for both consumers and society. Nanotechnologies enable the manipulation of matter at the nanoscale level that results in new properties and characteristics that can be beneficially exploited in food production and processing. Some of the potential benefits for consumers include foods with lower fat, salt or sugar levels that taste similar to conventional foods; improved packaging material that keeps food fresher for longer or tells consumers if the food inside is spoiled; and innovative food contact surfaces and materials that allow for improved food hygiene standards during food manufacture. There is also the potential to increase bioavailability of food additives and ingredients through the application of nanotechnology and to enhance the uptake of micronutrients in human and animal nutrition.

Nanotechnologies may also present new risks as a result of their novel properties. There are a wide variety of nanomaterials and while many of these may well prove to be harmless, others may present a risk to human health. Traditional food manufacturing processes result in the creation of nano-sized particles in emulsions and biological matrices that have been always present in foods. Such natural nanoscale substances have been consumed for many years without harmful effects being reported, for instance milk contains micelles ranging from 50 to 500 nm in diameter. On the other hand our current understanding of how engineered nanomaterials that are deliberately introduced into foods behave in the human body is not sufficiently advanced to predict with certainty impacts on human health. We have limited data on the functionality and toxicological impact of such nanomaterials, particularly in areas relating to the risks posed by ingested nanomaterials. Such information is required in order to ensure that regulatory agencies can effectively assess the safety of products before they are allowed onto the market. In order to properly develop, modify or in particular to implement legislation, our scientific knowledge base needs to be expanded and improved.

The introduction of nanotechnology in the food sector and its acceptance by consumers will depend to a large extent on the confidence people have in the effectiveness of regulatory systems in place to ensure that consumers are protected against any potential risks. The application and use of nanotechnology must comply with a high level of protection of public health and consumer safety, as well as protection of the environment. The regulatory challenge is therefore to ensure that society can benefit from novel applications of nanotechnology, whilst a high level of protection of health, safety and the environment is maintained. A reliable and stable regulatory framework is essential for enabling the food industry to fully exploit the advances and potential of nanotechnologies.

Food regulations

There are few areas in the nanotechnology debate that are under more scrutiny than regulatory considerations. It is an area that requires attention in the short-term as uncertainty over regulations for the use of nanotechnologies and nanomaterials in the food sector may stifle

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research and overall development. Key questions relate to whether current food regulations are sufficiently robust to be applied to nanotechnologies and whether risks can be dealt with under current legislative frameworks. At present there are no “nano-specific” food regulations in place but specific regulations are under development in various countries and regions. Global harmonised regulatory frameworks have not been developed but issues are being discussed at international level within the Organisation for Economic Cooperation and Development (OECD), the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organizations (WHO).

The broad areas of the food processing and manufacturing sectors with potential for the application of nanotechnology include food additives and ingredients, food packaging materials, food contact materials and novel delivery systems. The focus of regulation should be on engineered nanomaterials that are deliberately introduced into the food chain. Such engineered nanomaterials range from food contact material, ingredients and additives, to fertilizers and pesticides that are used in the food and feed area. Traditional nanoscale materials that occur naturally in food matrices should also be the focus of regulations if they have been deliberately used or engineered to have nanoscale properties or used in the manufacture of bioactive compounds.

A major challenge in the development of a regulatory framework for nanotechnology and nanomaterials is the absence of a common definition; agreement is required on what is being regulated if certain products or processes are not to fall between regulatory gaps. For the food industry to comply with regulations that govern nanotechnology there must be a clear definition of what they have to comply with so that they do not fall foul of compliance. In the interests of consumer protection a definition of nanomaterials should be added to food legislation to ensure that all nanoscale materials that interact differently with the body as a result of their small size are assessed for risk before they are allowed on to the market.

There are strong arguments that in the interest of protecting consumers’ health food legislation should ensure that all engineered nanomaterials used in the food sector undergo a safety assessment before they are allowed on to the market. Engineered nanomaterials are specifically designed and manufactured with the intention of being incorporated into food to fulfil a particular function. In this regard a regulatory definition of nanotechnology is required that is based on functionality of the engineered nanomaterial. The functionality is related to the novel size, shape, surface area and physico-chemical properties of the nanomaterial.

Current regulatory frameworks

A recurring question regarding regulations targeting the safe use of nanomaterials and nanotechnology in food and feed relates to the adequacy of current regulations to cover potential risks to consumer health. Food regulations already exist for food additives, micronutrients and essential elements, residues of pesticides and veterinary drugs, and for food packaging and food contact materials. Current regulations cover conventional foods where risks are assessed on a “macro-scale” for chemical ingredients, other components and contact materials prior to placing on the market. Additionally current regulations cover monitoring and surveillance programmes for residues and contaminants in the food chain which are based on established laboratory sampling and analytical methods. Many of our existing regulations were not designed with nanomaterials in mind so it is not surprising that provisions may not afford adequate consumer protection.

Current regulations cannot be directly applied to “nano-scale” ingredients or components in foods and modifications will be required to capture new developments in food processing and manufacture. Difficulties arise in characterising the properties of nanoparticles when attempting to carry out an estimation of consumer exposure. Difficulties also arise as analytical techniques to measure concentrations of nanoparticles in foods are not fully developed. Also limit values for nanoparticles cannot be expressed in weight or volume measures as is the case for conventional chemicals because of the altered functional properties associated with the size, shape, surface area and surface chemistry.

Different countries and regions are adopting different approaches. For instance in the European Union the general food law prohibits the placing on the market of unsafe foods where the responsibility is on the food business operator to ensure the safety of food products. New food ingredients and agents used in food and feed manufacture must be subject to a pre-market safety assessment. At European level regulations are evolving to include the utilisation of nanotechnology in foods, for instance a new regulatory requirement specifies that approved food additives that have been subjected to a size reduction to the nanoscale should be subjected to a new risk assessment before being placed on the market. In the United States any new foods or food ingredients are subject to pre-market safety assessment regardless of how they are manufactured. In Japan there are no specific requirements for nanotechnology in food regulations, however, current regulations ensure that only safe foods are placed on the market.

Research needs to support the regulatory base

There is a need to improve current scientific knowledge base to support the regulatory base. Current uncertainties for risk assessment are associated with the applications of nanotechnology in food and feed due to the limited information on methods to characterise, detect and measure nanomaterials and nanoparticles. Key areas where research is required are in the areas of the development and validation of reliable methods to measure relevant properties, such as size, shape, surface area and surface chemistry, particle size distribution, physiochemical and biological parameters in food different matrices. There is also a need to develop and validate methods to detect the effects of nanomaterials on human health to include acute and chronic toxicity, bioavailability, toxicokinetics, and exposure assessment. Similar research and development needs exist relating to persistence, bioaccumulation and degradation of nanomaterials in the environment and the development of regulations. It is important for governments and international agencies to cooperate and collaborate to ensure that knowledge gaps in research related to the health and safety risks of nanomaterials are filled quickly without duplication of effort.

Knowledge gaps impacting on development of regulatory frameworks

As applications of nanotechnologies and nanomaterials develop and become increasingly dissimilar to conventional technologies and materials, gaps in the current regulatory framework will become more pronounced. There are currently many areas of uncertainty surrounding the use of nanotechnology in the food and agriculture sectors that impact on the development of regulatory frameworks. These relate to a regulatory definition that should refer to the nanoscale with dimensions up to 1000 nm and to product functionality that defines how a substance interacts in biological systems.

When approved food additives and ingredients are reformulated at the nanoscale to confer new functional properties, such products should be subjected to a new risk assessment. Improved bioavailability of food supplements such as minerals and vitamins manufactured at the nanoscale may lead to redefining such regulatory concepts as acceptable daily intakes (ADI) or recommended daily intakes (RDI) in order to prevent risks of overdosing. The definitions of purity criteria will require information on the size and form of a substance.

With regard to regulations covering food contact materials, expressing regulatory migration levels in mass per mass or volume will not take into account the possibility of changing toxicity profiles with increased surface areas and smaller size. Regarding nanoscale food contaminants there may be a need to revalidate human health limits such as provisional tolerable weekly intakes (pTWI) or tolerable daily intakes (TDI) due to possible increased toxicity of nano-sized particle contaminants. Similarly additional safety testing or new approvals may be required where nano-particles are included in pesticides or utilised in veterinary medicines. The absence of routine analytical methods to detect nanoparticles in foods will hinder the application of monitoring and surveillance programmes that underpin the application of food regulations.

Where the risks posed by a nanomaterial cannot be fully determined, products should be denied regulatory approval until further information is available.

Title: A consumer group's point of view on the regulatory framework and nanotechnologies

Name: Sue Davies¹

Introduction

The use of nanotechnologies in food and agriculture has the potential to offer consumers a range of benefits, but could also present new risk unless developed responsibly and effectively regulated. At the moment it is difficult to assess the full implications of the technology. Fundamental knowledge gaps exist around what is already on the market and under development. There are also gaps in basic research which make it difficult to ensure robust risk assessment and the adequacy of regulatory oversight. These issues need to be urgently addressed and a more strategic approach adopted in order to ensure that nanotechnologies are developed safely and responsibly so that consumers can take advantage of the benefits without being put at unnecessary risk.

Key issues

Transparency

Many potential benefits from the use of nanotechnologies in food and agriculture are claimed, from improving quality and shelf life to nutritional benefits. But there is very little information about what is happening in reality, including what is already or close to coming on to the market and what could be seen in the future. The mainstream European food industry has stated that it is not currently using nanotechnology (UK House of Lords 2010), but a quick trawl of the internet reveals several products such as food supplements claiming to be using nanotechnology and available for consumers to buy.

The issue is compounded by a lack of clarity over what is classed as nanotechnology. International consensus is needed around working definitions, but this must not delay action to understand the status of developments and ensure that any risks are dealt with effectively. There now appears to be general acceptance that both size and functionality need to be taken into account.

This lack of transparency is problematic not only from a regulatory point of view, in that it means that it is difficult to ensure the adequacy of risk assessment and management measures, but also because it prevents meaningful, two-way risk communication.

Engagement

Public engagement in this area is essential on a number of levels. Consumers have a very personal relationship with what they eat and therefore have a right to know about key developments in the food chain and make informed choices about them. Effective engagement is also essential in order to ensure that the development of the technology and how it is regulated is in line with society's expectations and any concerns are addressed. There may be applications that consumers are particularly enthusiastic about, but it is also important to understand the limits of acceptability. Public acceptance is key to the successful development of a technology, as seen with the introduction of other novel technologies, most notably genetically modified (GM) foods. Failure to address consumer concerns can lead to a breakdown in confidence and trust in both the industry and regulators. As highlighted in the recent UK House of Lords' report into nanotechnologies and food (UK House of Lords 2010), an appearance of secrecy by the food industry is "*exactly the type of behaviour which may bring about the public reaction it is trying to avert*".

¹ Which?, UK

Research conducted by Which? in the UK has found that there is generally a low level of awareness of nanotechnology by consumers. A survey in 2007 (Which? 2007) found that 37 per cent had heard of nanotechnology. This had only increased slightly to 45 per cent in October 2008 (Which? 2008). Engaging the public can therefore be difficult. In November 2007, Which? organised a citizens' panel in order to try and gain a greater insight into people's reactions to the use of the technology, focusing on four main areas of development: food, medicines, cosmetics and general consumer products (Which? 2008a). The panel met over three days and heard evidence from a range of experts. This process indicated that despite coming from a range of backgrounds, people did become very engaged with the issues. They were open to developments, including in the food area although this is most sensitive, provided they are assured that there is an adequate regulatory framework in place to ensure the safety of products and enable informed choices.

The Which? research found that trying to ground public dialogue in specific examples as well as providing clear information about the different regulatory regimes enabled a fuller and more meaningful dialogue. The main recommendations from the panel are set out in Figure 1. In general the people involved were surprised that the technology was so advanced, although they had not heard of it, and they wanted the government to take a more comprehensive and strategic approach to its oversight, as summed up by the following comment from one of the respondents: *"It's like going out blindly into a blizzard – or actually sitting down with a map and thinking about where you are going to go"*.

Main conclusions from the Which? Citizens' Panel on Nanotechnologies (2008)

Safety: Panellists were concerned that products are on the market when scientists are uncertain of their safety.

Lack of regulation: Participants wanted regulation to deal with the risks nanotechnology raises and stressed the need for international action.

Information: There was concerned that there is no requirement to inform consumers about products using nanotechnologies.

Accessibility: It was questioned whether beneficial uses of nanotechnology would be accessible to all.

Environment: There was concern and interest in possible environmental impacts.

Ensuring safety

Unsurprisingly, safety was a major concern for the people involved in our research. Numerous reports from leading expert bodies since the UK's Royal Society and Royal Academy of Engineering reported in 2004 (Royal Society/ Royal Academy of Engineering 2004) have stressed that the novel properties of nano materials could present new risks as well as benefits and highlighted the need to address fundamental research gaps in order to enable effective risk assessment. While generally it is recognised that the current approach to risk assessment can be applied to nanotechnologies, key uncertainties in areas such as hazard characterisation and exposure assessment (EFSA 2009) make it difficult to be clear about the potential risks. These gaps are still not being addressed with sufficient urgency.

This raises fundamental challenges for the regulatory framework: it is essential that given their novel properties nano materials are subject to a pre-market safety assessment, but there are still outstanding questions about how that assessment should be conducted and how any requirement can be effectively enforced given the lack of clarity about market developments. As recognised within the Codex Working Principles for Risk Analysis (Codex 2007), it is also

important that approval processes also take into account 'other legitimate factors', which include broader social and ethical considerations, when determining whether a product should be placed on the market. Effective risk communication is essential in order to understand what these factors may be.

While debates around definitions, risk assessment and regulatory frameworks continue, consumers ultimately rely on enforcement officers at the local level to ensure that legislation is effectively enforced and that they are adequately protected. It is therefore important that legislative requirements are translated into clear guidance for enforcement bodies, as well as the food industry, so that once adopted, legislation is also complied with. Which? has for example found problems in the cosmetics area, where the safety of nano materials used in certain cosmetic products has been questioned by the EU's Scientific Committee on Consumer Safety, but there is a lack of awareness at a local authority level, making it difficult to ensure that potentially unsafe products are removed from sale.

Information, labelling and claims

Regulators also have a responsibility to ensure that the public is adequately informed about the use of nano materials in products. This is a difficult area as the usefulness of product labelling is often questioned in light of limited public awareness, leading to a circular discussion. However, consumers generally wish to know about the use of new technologies in food production and therefore it is important that they have clear information, supported by broader awareness raising of nanotechnology. Transparency across the supply chain is also essential in order to ensure that all actors are aware of the use of nano materials.

It is also important that products that claim to be produced using nanotechnology, actually are. While some manufacturers currently appear to be trying to avoid any association with nanotechnology; other products are actively promoted on this basis. It is therefore essential that consumers can trust any claims made about potential benefits on products and in associated advertising material. Where products do offer genuine benefits, accessibility is also an issue. As highlighted by the people in Which?'s citizens' panel: "*Inclusiveness is important – that these changes and applications make everyone's lives better*".

Challenges identified

They key consumer questions that arise in relation to the use of nanotechnologies can, therefore be summarised simply as follows:

- where are nano materials being used?
- how can consumers find out?
- how can we ensure or assess their safety given key knowledge gaps?
- how can consumers have a say in the development of the technology?
- which applications will bring genuine benefits?
- can consumers trust the claims some products are making?

Addressing these issues is compounded by the global nature of food production and supply and the increasing availability and purchase of products over the internet. International collaboration is essential in order to ensure that there is consistent and effective consumer protection around the world. It is also essential in order to fully understand what types of developments are taking place, those of most and least concern, to take advantage of genuine opportunities to help tackle the major challenges facing the food chain including food sustainability, non-communicable diseases, food safety and food security.

However, the benefits of international co-operation and co-ordination should not delay the important actions that need to be taken by national and regional governments in order to ensure that nanotechnologies are developed and used responsibly in food and agriculture. While there may be benefits in taking work forward through Codex, for example, to provide guidance on risk analysis for member governments, Codex's decision-making processes are slow and can all too often be weakened by too much focus on trade interests at the expense of consumer protection.

Strategies to overcome the challenges

Transparency

Poor experience of the introduction of other food technologies has meant that the food industry appears wary of speaking openly about its use of nanotechnology. This can only be counter-productive. If nanotechnology does have the potential in many areas as predicted, consumers should be made aware of this. Failure to be open about developments will arouse suspicion rather than prevent it.

It is therefore essential that the food industry is more open about its developments and that there is clear communication about the use of nano materials across the supply chain. Attempts at encouraging voluntary reporting of the use of nano materials, for example the UK's voluntary reporting scheme, have not been effective with very limited disclosure of information. It is therefore essential that governments introduce mandatory reporting schemes in order to enable them to assess the implications from a regulatory and risk perspective. This information also needs to be communicated in a more general form to consumers.

Policy makers also need to work with industry to determine the likely course of developments over the next 5, 10, 20 years and beyond, including possible applications of most and least risk and determine how the technology can be aligned with the main public policy challenges from obesity to climate change.

Engagement

The FAO/WHO expert consultation on nanotechnologies (FAO/WHO 2009) recognised the value and importance of effective stakeholder dialogue including that with the general public. There have been various initiatives, using different deliberative techniques from the type of Panel organised by Which? to larger, national debates which have met with varying degrees of success.

There needs to be an effective high-level dialogue between key stakeholders in order to assess the status of developments. But a wide range of techniques also need to be used to more effectively listen to, understand and respond to consumer reactions to developments at all stages of decision-making. This requires greater sharing of information and exchange at all stages of risk analysis. It also needs to focus on specific applications in order to better understand public priorities.

Ensuring Safety

Research needs to be further co-ordinated so that gaps can be addressed as a priority and a harmonised approach to risk analysis agreed, including agreement on working definitions while allowing some flexibility for them to be revised as understanding improves.

Gaps in regulations need to be urgently addressed so that nano materials have to be independently assessed and approved before marketing. Existing Codex guidance on risk analysis is important in this respect, but should be supplemented with more specific standards. Clear guidance also needs to be provided for industry and enforcement officers so that legal obligations are clear. Where there is uncertainty about safety, products should not be allowed on the market.

Many food applications that are relevant to the use of nanotechnology are, for example, subject to specific legislation in the European Union that requires a pre-market authorisation, including a risk assessment by the European Food Safety Authority (EFSA). Much of this has been, or is in the process of being updated to take account of the specific properties of nano materials and to clarify that materials in nano form require separate approval to their conventional form. The novel foods regulation is currently under review and there is support from both the European Parliament and Council to explicitly address the use of nanotechnologies. It is essential that there is clarity across all legislation relating to potential areas of application and that legal requirements are also translated into clear, unambiguous guidance for industry and enforcement officers.

Information, labelling and claims

Labelling of nano ingredients in the ingredients list should be a legal requirement, backed up by broader consumer information. This is now a requirement for cosmetic products in the European Union so it would be difficult to argue that consumers should not have the same information about ingredients used in food.

It is essential that genuine benefits are realised and offered to consumers. Involving consumers at an early stage when determining research priorities should help to ensure this. Broader social and ethical issues also need to be taken into account as part of the risk analysis process, in line with Codex guidance on the role of other legitimate factors. Claims about potential benefits also need to be substantiated and effectively policed by national authorities to ensure that consumers are not misled.

Conclusion

Nanotechnologies have the potential to offer consumers many benefits, but this will not be realised unless key research, risk assessment and regulatory gaps are addressed with greater urgency. Much greater transparency is needed around the status of developments in order to ensure effective regulatory oversight and meaningful public engagement.

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Which? (2008) Face to face survey of 977 adults aged 16+ representative of adults in the UK in October 2008.

Which? (2008a) Report on the Citizens' Panel Exploring Nanotechnologies, prepared by Opinion Leader. Opinion Leader Research conducted a Citizens' Panel on behalf of Which? with 14 members of the public. Panellists were selected broadly to reflect the general public and sat for three days from 29th November – 1st December 2007.