Nanotechnology – A CHEM Trust Position Paper

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Section 1: Summary of CHEM Trust's position on nanotechnology

CHEM Trust's position is that for regulatory purposes nano-materials (NMs) should be treated as new substances, which should be subjected to nano-specific legislation and nano-specific health and safety testing.

Marketing should not have been permitted until data on exposures and effects were adequate for a full safety assessment. An EU-wide mandatory pre-market approval scheme covering all sectors,[1] and requiring the provision of full safety data, should be brought in.

Hundreds of consumer products using nanotechnology are already on the market even though there are no specific regulations for their control. It is therefore important that consumers are allowed to exercise their right to avoid NMs, and to this end, all products should be required to be labelled with constituent NMs.[2] In the EU, CHEM Trust considers that there is an urgent need for a comprehensive public inventory of NMs which are used in consumer products, along with the products in which they are found. Given the current situation whereby NMs are already used in many products, there should, at least, be post-marketing surveillance and measures to ensure manufacturer liability should any problems arise.

[1] Some industry sectors are already covered by a pre-market approval system (eg. novel foods, food additives, feed additives, plastic food contact materials, medicinal products) (see EC, 2012).

[2] Nano-ingredient labelling has been introduced in some (but not all) products of relevance to consumers (eg. food and cosmetics) (see EC, 2012).

CHEM Trust's conclusions are that:-

- there are insufficient data on the long term environmental implications and the potential health effects of NMs, particularly including effects on the unborn child during development in the womb, and effects on brain function.
- the nanotechnology sector is irresponsible for marketing NMs before fully assessing their safety and for not providing sufficient safety data on their products for both the regulatory authorities and the public. Similarly, governments have been negligent of their duty to protect human health and the environment by not requiring adequate prior safety testing.
- new NMs should not be allowed on the market until industry has provided adequate safety data on the exposure and effects of the chemical, in the form to be marketed.
- a dedicated nano-specific framework legislative instrument is needed, as this could address all aspects of this new technology. However, if this is not forthcoming, NMs should at least be treated as new chemicals under EU legislation, and appropriate prior testing procedures, notification and labelling should be imposed by all the various pieces of legislation currently relevant for NMs.

Section 2: What is nanotechnology and why is it different?

Nanotechnology is a new and quickly developing field that involves the manufacture and use of very small forms of chemical compounds. NMs are typically less than 100 nanometres (nms) in size in at least one dimension, and are named nano because they are measured in units of 10^{-9} of a metre.[3]

This is a technology built on the atomic scale, and for comparison, a strand of human hair is 80,000nms, so NMs are at least 800 times smaller than the width of a hair. NMs can be spherical, tubular, or irregularly shaped and can also exist in fused, aggregated or agglomerated forms.

Some types of NMs can be formed during burning and so we have been exposed to them for thousands of years, and also some nano-structures have now been found to be naturally present in common foods like ice-cream (HM Govt, 2010), but *engineered* nanoparticles, based on many different chemicals, are a very new phenomenon. Engineered nanoparticles can also be 'functionalized', whereby there is additional chemical modification of the nanoparticle surface, to enhance its suitability for various uses.

[3] In 2011 in the EU, a Commission Recommendation (2011/696/EU) defined 'nanomaterial' as:
"a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm-100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

Nanotechnology is of great concern because the reactivity of a material is related to its surface area. Dissecting a 1 centimetre cube of any material into 1 nanometre cubes increases the total combined surface area some ten million times. NMs are therefore much more reactive than larger volumes of the same 'parent' substance, and can even have very different properties (Lloyds, 2007).

Section 3: The nanotechnology market

Nanotechnology represents an entirely new engineering field, which spans many products. Conservative estimates are that global revenue for nanotechnologies will grow from around $2x10^9$$ (2,000,000,000) in 2007 to 81 x $10^9$$ in 2015 (HM Govt, 2010). Furthermore, some estimates suggest that, at least in some countries, 15% (by value) of all products will contain nanotechnology by the year 2014 (Lloyds, 2005). At present, the majority of nanotechnology occurs in the United States, followed by the EU, with 30% of the global share of this sector. Within the EU, the UK accounts for nearly a third of that total (CSL, 2007). In terms of the total number of nanotechnology companies operating, the UK is ranked 3rd in the world, after the US and Germany, with its particular strength being nano-optics, where it is again ranked third, but this time after the US and Japan (HM Govt, 2010).

A 2007 UK study indicated that only a few sectors (e.g. paints and coatings, cosmetics, catalysts, polymer composites etc.) were using NMs in any significant quantities (CSL, 2007). However, with new applications and markets, this situation is rapidly changing. As of 2010, it was estimated that there were around 800 nanotechnology products or product lines on the market globally (HM Govt, 2010), with, as of 2012, some 300,000 to 400,000 workers employed specifically in nanotechnology in the EU alone (EC, 2012).

The current and projected applications of NMs include catalysts, lubricants and fuel additives; paints, pigments and coatings; cosmetics and personal care products; medical, dental, drug delivery and bionanotechnology; functional coatings; hydrogen storage and fuel cells; nanoelectronics and sensor devices; optics and optic devices; security and authentication applications: structural (composite) materials, conductive inks and printing; UV-absorbers and free-radical scavengers; construction materials; detergents; food processing and packaging; paper manufacturing; agrochemicals, including pesticides and veterinary medicines; plastics; and weapons and explosives (CSL, 2007). UK companies appear to be most active in the market sectors of coatings and inks, biotechnology, speciality chemicals, electronics, sensors, instrumentation, and medical devices (HM Govt, 2010).

In terms of the chemicals, the nanotechnology market is dominated in tonnage by carbon black and synthetic amorphous silica. Other NMs with significant amounts on the market include aluminium oxide, barium titanate, titanium dioxide, cerium oxide and zinc oxide. Carbon nanotubes and carbon nanofibres are also currently marketed, as is nanosilver. However, there are a wide variety of NMs either at the research and development stage, or which are marketed only in small quantities.

A variety of consumer products that contain NMs are therefore already available in the UK and the EU. Examples of these include self-cleaning glass, anti-microbial wound dressing, paints and coatings, fuel catalysts, sporting goods and cosmetics. Inventories featuring many of the consumer products using NMs are maintained by the 'Project on Emerging Nanotechnologies' which was established in April 2005 as a partnership between the Woodrow Wilson International Center for Scholars in the USA and the Pew Charitable Trusts (http://www.nanotechproject.org/inventories/). Whilst some data are available on the concentrations of NMs in selected products, for some products this is lacking.

Nanotechnology undoubtedly has the potential to deliver some environmental solutions or health benefits, and for example, there are developments using NMs in vehicle efficiency, solar power, asthma monitors and drug delivery systems. However, as is usual with any new technology, it seems that it is difficult to restrict its uptake to those areas where real societal benefit may accrue, or to delay its penetration until safety concerns are properly evaluated. Particularly during a time of economic recession, governments want to help companies under their jurisdiction to grow and successfully compete in world markets; this acts as a pressure against adequate regulatory oversight.

Section 4: The environmental and human health concerns

CHEM Trust is particularly concerned that the long term health and environmental effects of NMs are generally unknown. Therefore, CHEM Trust has major concerns about the safety of nanotechnology, both for workers, the general public, and the environment.

More information is needed about the effects of NMs on soil systems and on microorganisms in sewage treatment plants. There is also a lack of information about how NMs might affect wildlife, including marine species. For some NMs, toxic effects on organisms have been shown, as well as the potential to transfer across environmental species, indicating a potential for bioaccumulation in certain species (SCENIHR, 2009). NMs may also interact with other contaminants to cause toxic effects on biota (SCENIHR, 2009), but even their effects by themselves are not well characterised. The risks posed by the extensive use of nanosilver for its biocidal properties, for example, are not fully understood, but silver nanoparticles are known to be highly ecotoxic, particularly in the aquatic environment (EC, 2012). Furthermore, a report by the UK Advisory Committee on Hazardous Substances (ACHS) has drawn attention to some uncertainties, including possible increased antibiotic resistance (ACHS, 2009).

It is important to remember that as many NMs are likely to be used in a range of product types and the environment will be exposed to all of these, environmental risk assessment needs to consider all sources and possible additive effects or interactions.

For humans, exposure might arise via inhalation, ingestion or dermal application. The worries about inhaled NMs in tubular form (eg. carbon nanotubes) include whether they might cause lung damage similar to asbestos fibres. Some concern also exists with regard to the possible effect of NMs on the cardiovascular system and the immune system (see Seaton et al.,2009; Dobrovolskaia & McNeil, 2007).

Given the small size of NMs, they may be transported to various organs in the body and all organs may be at risk from certain nanoparticles. CHEM Trust is particularly concerned about the possibility of effects in the brain or the developing foetus. Research already suggests some NMs may get to the brain, perhaps via transport from the lining of the nose (Oberdorster et al, 2004). A recently published study suggested that carbon (in the form of nano bucky balls) induced oxidative stress in the brains of fish exposed to 0.5 ppm for 48 hours (Oberdorster, 2004). NMs have also been found to alter protein aggregation in 'test-tube' or '*in-vitro'* tests, fuelling the concerns that if such activity can occur in the body, they might play a role in amyloid diseases, such as Alzheimers (SCENIHR, 2009).

The carcinogenic potential of NMs also needs to be investigated fully, as for example, NMs may be able to enter the nucleus of cells where they could interact with the DNA to cause genotoxic effects (Garcia-Garcia et al., 2005; see SCENIHR, 2009). However, a summary of all the worrying research is beyond the scope of this position paper, and it needs to be borne in mind that different NMs may cause different effects, and effects may depend on their size, their coating, as well as the parent chemical from which they are derived.

In conclusion, adequate data to fully evaluate the risks that NMs pose to the environment and human health are not available. Not only is the long term toxicity of many NMs currently largely unknown, but also there is a lack of good exposure data for both humans and the environment. It is likely that the risks posed by NMs in the form of free particles (eg. in powders or liquids) are greater than those from NMs fixed into a structure, which limits the likelihood of them entering the human body or the environment. However, it is not yet clear whether fixed NMs (eg. in a solid material like a plastic or in a coating) will remain fixed when the item they are incorporated into is disposed of. Furthermore, in real life situations, monitoring the actual exposure to *engineered* NMs is generally difficult, as current methods mostly measure the presence of NMs, and do not generally discriminate between the different types of particles (*engineered* or naturally occurring) that may be present (SCENIR, 2009). CHEM Trust considers that companies manufacturing NMs should have developed the analytical methods to track their products in the environment, prior to marketing, and furthermore, should have fully understood their fate and behaviour.

Section 5: EU regulation of and deliberations on NMs

Currently, NMs are not regulated by a single, specific regulatory framework, but rather under many different regulations which relate to various sectors or products. Indeed, the Royal Commission report (RCEP, 2008) listed some 62

instruments under which NMs may fall. These include, for example, laws relating to novel foods, additives, food contact materials, cosmetics and industrial chemicals, some of which have been updated to better address NMs. For example, the new 2012 legislation relating to biocides[4] now specifies that the approval of an active substance does not include the NM form, unless explicitly mentioned. Further on 11th July 2013, the updated EU Regulation on cosmetic products enters into force[5], and this requires manufacturers of any new cosmetic products containing NMs to notify the Commission, six months prior to them being marketed, and similarly, products already on the market prior to this will also have to be reported by July 2013. Nevertheless, there are still concerns about the nano-provisions of this Regulation, as for example, they only relate to bio-persistent or insoluble materials.

For industrial chemicals, NMs will be considered to be 'existing substances', if the 'parent' chemical, from which they are derived, was already on the market before 1981. Nevertheless, under the EU regulation which deals with industrial chemicals (the REACH Regulation (1907/2006) concerning the Registration, Evaluation, Authorisation and Restriction of Chemical substances**),** any new use of a substance, such as in a nano form, should be reported along with any information that is relevant for risk assessment. However, unfortunately many registrations for substances known to have NM forms do not mention clearly which forms are covered. Furthermore, a study has shown that there is only scant information addressing safe use of the specific NMs supposed to be covered by the registration dossiers (EC, 2012). The REACH Competent Authority Sub Group on Nanomaterials is responsible for addressing some of the key issues in implementing REACH for NMs, and the UK is represented on this group by the Health and Safety Executive (HSE). The European Chemicals Agency (ECHA) has also set up a Group Assessing Already Registered NMs (GAARN), to consider a few key NM registrations, in cooperation with the Commission, Member States' experts and stakeholders. The purpose is to identify best practices for assessment and reporting of NMs in REACH registrations and to develop recommendations on how to fill potential information gaps. In addition, ECHA has set up a NMs Working Group to give advice on scientific and technical issues in relation to NMs under REACH.

CHEM Trust considers that a dedicated nano-specific framework legislative instrument, that could address all aspects of this new technology, would be the best option. However, if this is not forthcoming, NMs should at least be treated as new chemicals under EU legislation, and appropriate prior testing procedures, notification and labelling should be imposed by all the various pieces of legislation currently relevant for NMs. Several environment and health organisations have called for a stand-alone regulation on nanotechnology to close the many current loopholes, and have furthermore outlined the needs of a so-called 'nano-patch' (ClientEarth et al.,2012).

[4] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
[5] Regulation (EC) No 122/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

The EU REACH Implementation Project on Nanomaterials (RIP-oNs 2) in 2011 concluded that provided various issues related to sample preparation, delivery and dosage monitoring were given due consideration, the current OECD toxicity test methods (as used for non-nano chemicals) were still adequate for assessing NMs. CHEM Trust disagrees with this, and considers that a range nano-specific test methods need to be developed.

The EU has made some moves to try to address nanotechnology in an integrated way and nearly a decade ago, back in May 2004, the European Commission adopted a Communication "Towards a European Strategy for Nanotechnology" (COM(2004)338). In 2010, the Commission subsequently consulted on the development of a new updated action plan, to be called the "Strategic Nanotechnology Action Plan 2010-2015" (EC, 2010).

The European´s Parliament Resolution of 24 April 2009 on regulatory aspects of NMs has also pushed forward the issue (EP,2009), and has called on the EC *"to review all relevant legislation within two years to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle, and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed"* (5) It also called for "*the Commission to compile before June 2011 an inventory of the different types and uses of nanomaterials on the European market, while respecting justified commercial secrets such as recipes, and to make this inventory publicly available; furthermore calls on the Commission to report on the safety of these nanomaterials at the same time;"* (16)

In December 2010, the Environment Council also adopted conclusions that called on the Commission to "*evaluate the need for the development of specific measures for nanomaterials relating to risk assessment and management, information and monitoring, including the further development of a harmonized database for nanomaterials…"*

A review of EU legislation in relation to NMs, published in 2008 (COM/2008/0366 final) (EC, 2008), highlighted the need for improved implementation of current legislation. Furthermore, although it was considered that current legislation covered, in principle, the potential health and environmental risks of NMs, it was clear that knowledge about hazards, exposure, risk assessment and risk management of NMs needed to be improved (EC,2008). A subsequent regulatory review, published in October 2012 (COM(2012) 572 final) (EC,2012) highlighted that, with respect to consumer product regulation, the main challenge still remained the ability to undertake a proper risk assessment. It also noted that the Commission will, in future, try to identify and develop means to increase transparency and ensure regulatory oversight, including an in-depth analysis of the data gathering needs for such purpose. This analysis will include those NMs currently falling outside existing notification, registration or authorisation schemes. The 2012 review concluded that *"important challenges relate primarily to establishing validated methods and instrumentation for detection, characterization, and*

analysis, completing information on hazards of nanomaterials and developing methods to assess exposure to nanomaterials."

In response to the European Parliament's concern that the Commission's approach to NMs is jeopardised by a lack of information on the use and on the safety of NMs that are already on the market, the 2012 regulatory review was accompanied by a Commission Staff Working Paper (SWD, 2012) on types and uses of NMs. This also looked at safety aspects and included information about databases on NMs.

Section 6: Research and controls in the UK

With regard to the safety of NMs for human health, in 2005, a UK Government report identified several priorities, including: to understand how NMs can enter the human body; where they go within it; and their toxicological and disease-causing effects associated with important places of entry into the body, such as the respiratory system, skin and gut (HM Govt., 2005).

Research on nanotechnology has been overseen by the Nanotechnology Research Co-ordination Group (NRCG) and its Task Forces, and the Department of the Environment Food and Rural Affairs (Defra) has published the results of several research projects since the Government's first report in 2005. One research project, in particular, highlighted that current testing strategies are not fit for properly evaluating the threats this new technology may pose to wildlife (Watts & Crane, 2007). Following this, the 'EMERGANO' project published in 2009 looked at global research into the environment and health implications of nanotechnology (EMERGANO, 2009), and there is now an on-going portfolio of Government and publicly funded research into the behaviour of key NMs.

Some progress has undoubtedly been made in evaluating the potential risks involved with nanotechnology, and the UK has put in place various initiatives (eg. the Ministerial Group on Nanotechnologies and the Nanotechnology Research Strategy Group) to look into the concerns as well as to gain better understanding of the industry. For a short time, Defra operated a voluntary reporting scheme to try and get information about which NMs were being marketed in the UK. This scheme ended in September 2008 (HM Govt, 2010) perhaps because being voluntary, it never achieved broad uptake. In contrast, France has now adopted legal measures to impose a mandatory reporting scheme.[6]

The UK Government published its 'Nanotechnologies Strategy: Small Technologies, Great Opportunities' in March 2010, which promised a coordinated web portal to summarise what the UK Government is doing on the issue. However, unfortunately such a comprehensive website is not going to be set up, and the explanation for this is that the undertakings given in the

[6] See http://www.safenano.org/KnowledgeBase/CurrentAwareness/ArticleView/tabid/168/ArticleId/194/France-to-introduce-mandatory-reporting-of-nanomaterials-in-2013.aspx

2010 strategy report were those of the previous administration, which the coalition Government has chosen not to adopt in totality. However, the UK coalition Government has set up a new multi-stakeholder Nanotechnology Strategy Forum, chaired by Business, Industry and Skills (BIS) and Defra Ministers[7] (see http://www.defra.gov.uk/nanotech-forum/)

Section 7: Global concerns

In September 2008, 70 governments, 12 inter-governmental organizations, and 39 non-governmental organizations (NGOs) participating in Forum VI of the Intergovernmental Forum on Chemical Safety (IFCS) adopted the Dakar statement on nanotechnology and manufactured nanomaterial. Although not legally binding, two particularly important points were made:

> *"In order to strive to achieve the minimization of risks of manufactured NMs, the rights of countries to accept or reject manufactured NMs was recognised."(10)*
> *"Producers to provide appropriate information about content of manufactured NMs in order to inform consumers about potential risks, through product labelling, and as appropriate, websites and databases."(18)*

These are fine sentiments, but the ineffectiveness of the UK and other governments is only too evident, in that NMs in products are not labelled, such that consumers are the subject of a global experiment because they are unwittingly exposing themselves to products that have not been properly assessed for safety.

In May 2009, under the Strategic Approach to International Chemicals Management (SAICM) a UNEP level Resolution was agreed which recognised nanotechnologies and NMs as an emerging policy issue. The Global Plan of Action (which acts as a guidance document and working tool) has therefore been updated by including activities relating to nanotechnology.

Another key international initiative on NMs is on-going within OECD, which particularly focusses on getting agreement on test methods and the international acceptance of safety data. In 2006 the OECD Working Party on Manufactured Nanomaterials (WPMN) was established, bringing together relevant Ministries and Agencies responsible for human and environmental safety, as well as stakeholders. A formal four-year programme of work was endorsed by the OECD Chemicals Committee to cover the period 2009 to 2012, and this aimed at the development of a globally harmonised approach to the management of NMs (WPD, 2012).

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[7] See http://www.defra.gov.uk/nanotech-forum/

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