

RSC submission to the RCEP Consultation on the Environmental Effects of Novel Materials and Applications

The RSC welcomes the opportunity to respond to the Royal Commission on Environmental Pollution study into the *Environmental Effects of Novel Materials and Applications*.

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This document represents the views of the RSC. The RSC's Royal Charter obliges it to serve the public interest by acting in an independent advisory capacity, and the RSC is happy for this submission to be put into the public domain.

Where deemed appropriate, the RSC has chosen to group questions together to provide a coherent response, and has chosen to answer those questions deemed most pertinent.

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THEME 1: Scene-setting: what are novel materials and what developments are likely over the next 5 – 10 years? Which ones should be investigated for the purposes of this study?

1. *What do you understand by the term novel material? How might novel materials best be classified? What novel materials should be included in the study?*
- 3 *What sort of novel materials and technologies are being developed -over the next 2, 5 and 10 years?*

Novel materials could be viewed as completely new materials that have been developed in isolation from others, *i.e.* they are un-connected to materials already in use. More realistically, novel materials will include a more diverse range, including some already in use, materials that are linear developments of those already known, and established materials deployed in new applications. In order to provide a comprehensive answer to the consultation, it is the latter, approach that we have taken as it is unrealistic to predict the nature of truly novel, as yet unknown, materials.

The properties of novel materials can arise from two key factors: first, the chemical composition of the material and, second, the physical size and shape of the material. As scientists are increasingly able to exert ever more sophisticated control over molecular-level organisation the morphology of materials is becoming increasingly important.

Gold provides an illustrative example of how physical properties can have a very substantial influence on chemical properties. In the bulk phase gold is inert, but on the nano-scale it is highly reactive. The chemical composition of these two materials is identical, and it is the change in physical size that gives rise to the change in properties.

In defining novel materials it is also useful to consider the intrinsic properties of the material arising from its chemical composition, the properties of materials formed from this material, and the potential applications of the material.

This can be illustrated by considering superconducting perovskites developed in the 1980s. Intrinsically these materials possess highly novel properties as a result of their elemental composition, allowing for superconduction at temperatures higher than those known previously. However, the limitation of these materials is in their bulk properties; they are synthesised from powders into brittle solids that cannot be formed into elongated wires. In conclusion, the intrinsic properties and potential applications are highly novel, but limited by their materials properties.

The RSC responded to the initial RCEP scoping consultation and suggested the following materials classifications:¹

- Polymers
- Solid-state ceramics
- Glasses
- Metals and alloys
- Nanoparticles, nanotubes and colloidal materials

- Liquid crystals
- Composite materials

Unfortunately, some materials will slip through these categories, especially those which are novel by virtue of being applied to completely new applications, e.g. well-known metal hydrides being used for hydrogen storage.

Classification by broad themes in which the end-use is considered could also be effective, despite the potential for significant cross-over between categories. The RSC suggests the following broad themes could be useful:

- *Energy generation, storage and fuels*
- *Energy efficiency*
- *Engineering materials*
- *Construction Materials*
- *Biocompatible Materials*
- *Environmental applications*
- *Electronics and Display technologies*
- *Food packaging*

This classification can also be useful when considering environmental and health effects as it gives some indication of exposure routes. For example, biocompatible materials placed in the body will have a very different exposure route to materials used in building construction.

By way of illustration we have expanded two of these themes: *Energy generation, storage and fuel*, and *Biomaterials*, although the evidence contained should not be considered exhaustive.

Energy generation, storage and fuel sources

Materials used for energy generation or storage will become increasingly important with global concerns regarding energy demand, climate change, limited resources and energy dependency.

Photovoltaics (PVs) involve conversion of sunlight into electric current. Although these are now commercially available, there remain concerns about improving efficiency, decreasing the usage time before energy expenditure during manufacture is exceeded, and life-cycle analysis, amongst others. Materials of interest include:

- Conductive organic polymers
- Inorganic semi-conductors: indium tin oxide (ITO), cadmium selenide (CdSe), copper indium diselenide (CuInSe₂), amorphous silicon, thin film silicon and titanium dioxide (TiO₂)
- Inorganic semi-conducting nanoparticles: including CdSe and lead sulphide (PbS).
- Fullerenes

Lithium ion batteries have presented major advance in battery technology and are found in numerous portable, rechargeable electronic devices, e.g. laptops, mobile phones. Scale-up to larger batteries requires cheaper, safe electrode and polymer electrolyte materials with better performance, amongst other requirements. Cathode materials under investigation, and potentially delivering improved performance over LiCoO_2 cathodes currently in use, include $\text{LiNi}_{1/3}\text{Co}_{1/3}\text{Mn}_{1/3}\text{O}_2$, LiMO_2 and LiMPO_4 ($M = \text{Mn, Fe}$). Anode materials are currently satisfactory and will cope with increased cathode performance, but in the long term they will need to be improved to keep up with higher performance cathodes. Recent improvements include lithium and tin alloys, and titanium dioxide nanowires.

Superconducting magnetic energy storage devices (SMES), in which energy is stored in a magnetic field within which a current flows, hold much promise for electricity storage. The coil is typically composed of niobium with titanium or tin and has to be cooled below the critical superconducting temperature of around 268°C . For this technology to be commercially viable it will require materials that can operate at higher temperatures, preferably room temperature, and with mechanical properties that allow for processing into wires or coils.

Hydrogen storage could provide an alternative to electrical storage, with higher energy densities achievable. It would also need to be a key component in any hydrogen powered transportation. Both gaseous and liquid hydrogen storage present problems, although compressed hydrogen gas may be a medium term solution despite the significant drawback of a low energy density. Any material-based hydrogen storage medium must have easily reversible hydrogen binding and release, low weight, and high volumetric and gravimetric hydrogen content. Currently, it remains unclear which technology will be implemented in the long term.

- Many inorganic metal hydrides are known chemically, but this represents a new and novel use of these materials (based typically on platinum, palladium, nickel, or magnesium). Significant drawbacks are the very large exothermic chemical reaction upon binding hydrogen which requires rapid heat dissipation, the need to heat the material to obtain hydrogen release, and the use of reactive metals, such as magnesium. Currently hydrogen storage in these materials lies at approximately 3.5 – 4 %. Complex hydrides, such as LiAlH_4 , may hold greater potential for storage, but heat dissipation and hydrogen release both remain problematic.
- A number of alternatives rely on physisorption processes in high porosity materials with high surface areas. These include metal organic frameworks (MOFs), activated carbons and polymeric materials. Heat of physisorption is substantially less than that for inorganic hydride formation (approximately 5 kJ g^{-1} versus 40 kJ g^{-1}), although heat dissipation is still a problem. These materials also require low temperatures for hydrogen insertion (77 K), but theoretically they could be loaded to as high as 10 % by weight.

Materials also play a key role in harnessing wind, tidal and wave power. High strength, lightweight materials for turbine blades and towers are required in order to facilitate the construction and continued operation of large power turbines. Protective surface coatings will also be required to reduce maintenance costs and prolong the lifetime of wave and tidal energy devices.

A more speculative use of novel materials in energy applications is the proposed use of metal and metalloid nanoparticles as solid fuel sources. This makes use of high oxidation and reduction processes; relative to hydrogen, iron as a seven-fold energy release per unit volume, and aluminium a nine-fold, and boron a sixteen fold energy release. The majority of this research is still theoretical, although preliminary experiments have been carried out at Oak Ridge National Laboratory, USA.² In the shorter term, metal nanoparticles are likely to find uses as combustion catalysts for solid and liquid fuels in the automotive field. A recent example is the development of the cerium oxide nanoparticle based system ‘Envirox’, developed by Oxonica, to improve fuel consumption and decrease harmful emissions.³

Biocompatible Materials

Tissue engineering utilises materials in conjunction with biological factors to replace, or improve, biological functions. It is of great current interest and is likely to have a significant impact in the healthcare and medical sectors. It is concerned with the creation and application absorbable scaffolds which can stimulate tissue growth. Based on the physical form, rather than chemical composition, we can broadly categorise the materials currently being developed into the following:

- Foams are typically used as bone scaffolds, and can be constructed from, for example, hydroxyapatite, polyurethanes, acrylic polymers and natural polymers, such as chitosan.
- Fibres are highly porous materials that can be used as scaffolds for cell growth. Typically, cells from a patient would be grown on these scaffolds in a laboratory and then implanted, although more futuristically, fibres modified with cell growth or cell adhesion factors would be implanted directly into a patient. These fibres can be produced from a range of biocompatible materials such as polylactides, polyglycolides, polyesters or collagens. Once implanted it would be anticipated that they either degrade or stay in place in an inert form.
- Biocompatible coatings, usually polymeric in nature, are essential for the use of bioimplants. Mechanical properties are often the key consideration in designing bioimplants, such as artificial hips or engineered blood vessels, but they often have poor biocompatibility properties. Coatings, such as biocompatible hydrogels, are employed to ensure the implant is integrated successfully.

It is noteworthy that materials from several of the original materials classifications feature within any one application, and some that were originally omitted are now included.

The RSC would also direct the Commission to consider the SusChem Implementation Action Plan 2006⁴ and the Royal Society’s report *Nanoscience and nanotechnologies: opportunities and uncertainties*⁵ as further sources of information on novel materials. The RSC has been active in the area of energy, and further relevant information may be found on *Materials for Nuclear Waste Management*⁶ and *Renewable Energy – Generation Technologies*.⁷

The RSC also has a number of Interest Groups with specialities in all the areas listed above, and can provide further information and contacts if required.

4. *What are the drivers for the development of novel materials? What are the potential benefits of novel materials and the drivers for these?*

The drivers for the development of novel materials are societal: health, quality of life and cost effectiveness.

The balance of these factors can decide whether or not a novel material is implemented for a specific application. It remains unlikely that, for example, new materials for application areas as critical as energy will be adopted if the financial cost is too high.

There is currently an ongoing search driven by health concerns to replace lead bearing compounds in electronic devices. They are currently used in an extensive range of applications; an example is the piezoelectric lead zirconate titanate PbZrTiO_3 . Considerable work is ongoing, and dominated by Europe, to find non-lead based alternatives. Currently, the properties of these novel materials are not as good as those based on lead, but this situation may well change as a result of future breakthroughs.

It should also be noted that some of the novel materials described in answers to questions 1 and 3 may themselves be superseded by different materials based on health and financial implications. Elements such as cadmium, selenium and indium, being developed for use in photovoltaics, and tellurium, bismuth and lanthanum in magnetic storage devices, are all considered toxic. Whilst they may not necessarily be especially hazardous, problems could arise during the manufacture of these materials, especially the need to avoid contamination via waste water streams, for example, and during their recycling and end of life (see question 5). More work needs to be undertaken to investigate these challenges and, if necessary, identify alternative novel materials based on less toxic constituents.

A specific example of costs driving innovation is the use of silicon transistors in liquid crystal displays (LCDs). Whilst silicon technology is well-understood from the semi-conductor industry, the use of silicon transistors in this scale of device remains expensive, energy intensive and the chemicals used can be highly corrosive, thus limiting the nature of the substrate. There is a desire to move away from silicon processing and towards printing technologies, which could achieve large area capabilities, high processing speeds and low energy input. Conducting polymers, tin oxide semiconductors, silicon nanorods and carbon nanotubes are all being considered.

Replacement materials are also being sought for indium tin oxide (ITO); an inorganic semi-conductor used in photovoltaics, LCDs and OLED devices. Limited global reserves (see also question 5) are leading to ever increasing costs. The choice of alternative materials is still speculative, although antimony-based materials and doped tin oxides are being investigated.

If replacement materials could be found for both of these examples, it could be envisaged that costs for such devices would drop and for ITO in particular, a resource could be protected.

5. *Can the development of novel materials have an impact on resource depletion?*

This is almost certainly going to be an issue for future materials development. Often unique materials properties arise from the incorporation of chemical elements that have a low natural abundance.

One example is the continuing use of indium tin oxide (ITO) in PV and electronic devices, despite the fact that this is a highly limited resource and that costs are escalating.

Cobalt oxide comprises one quarter of the mass of lithium ion batteries and is a key component in the functioning of the cathode. Global reserves of cobalt are small; less than a tenth of that for nickel and just over one hundredth of that for copper. If 30 million battery packs capable of powering electric vehicles were made annually then world cobalt reserves, assuming the estimates are correct, would be exhausted in six years. The majority of cobalt reserves are located in politically unstable regions; the top three sources are based in the Congo, Cuba and Zambia.

- 6. *Are issues of re-use and recycling considered when developing novel materials – e.g. could the phasing out of metals for composites make recycling difficult?***
- 7. *Are materials likely to alter the amount of waste generated and the ways in which it has to be handled?***

Novel materials, especially those in the development phase, offer an opportunity to develop sustainable manufacturing processes and sustainable supply chains. New materials, in many cases, have potential environmental, economic and societal benefits over conventional materials. This includes energy efficiency, reduced fuel consumption, improved communication and reduced waste.

To fully understand the implications of the manufacture, use and end-of-life of novel materials the RSC recommends that life cycle assessment (LCA) is applied during their development and used to minimise environmental impacts and maximise economic and societal benefits.

LCA methods can be used to assess materials and energy flows throughout the life cycle of a given product or process. They can be used to identify environmental impacts, inefficient processes, high-energy use and exchanges of materials with the environment. LCA does not, however, give an indication about how to best act upon the observations. Theoretical LCA studies could be used to predict life cycle implications for novel and advanced materials and for comparing alternative processes and supply chains with respect to environmental impacts. There is still work required on developing internationally standardised and unbiased LCA methodology that can be used for comparative studies.

The information that LCA provides on materials flows could be used to indicate how, where and in what quantity novel materials or their by-products might be expected to end up in the environment.

THEME 2: Environmental and health impacts of novel materials

- 10. *Do we have sufficient research and monitoring in terms of understanding toxicology and exposure in place in order to understand the effects of novel materials on the environment and human health?***
- 11. *Are current testing protocols 'fit for purpose' to test the environmental and health impacts of novel materials? If not, what needs to be developed or are there other strategies needed to address this issue?***

Currently we do not have sufficient information. In some cases the methods to acquire the data needed to understand the toxicology and exposure routes of novel materials (*i.e.* materials which have not been seen before or new forms of existing materials) are absent or are not sufficiently standardised.

What is not yet understood is what kind of environmental and toxicological effects would be expected. Will novel materials give rise to novel, as yet unknown, environmental effects, or will they simply give rise to known effects, potentially to a different extent, when compared to established materials and chemicals? The latter could be suggested by, for example, the use of nanoparticles in medical treatments which are used to enhance known treatments rather than introducing new therapeutic benefits.

It is unlikely that current testing protocols will provide appropriate data to ascertain any novel, as yet unknown, toxicology of new materials, especially those on the nano-scale. Current testing protocols are usually fairly coarse screens for known effects, and in some cases they identify that an effect (*e.g.* endocrine disruption) exists without toxicologists and regulators knowing how to interpret the data in terms of regulatory action. Undoubtedly, new nanoparticles, for example, should be subjected to a different range of studies to those currently in existence. As highlighted in Theme 1, it is not only the chemical composition but also the physical form of a material that needs to be evaluated. Different morphologies have been demonstrated to lead to different chemical reactivities, and this in turn is likely to lead to different biological effects. The assessment of environmental and health impacts of novel material will also require the identification of appropriate biomarkers.

Difficulties arise when considering that the form of the materials that may make its way into the environment may not be the same as the form encountered during in manufacture. For example, many nanoparticles will agglomerate in the natural environment into larger structures and react in a similar way to the bulk material rather than exhibiting the properties of the nanoparticles. The issue of likelihood of release into the environment also needs to be considered. For example, the erosion of photovoltaic cells placed on rooftops is unlikely to lead to the release of nanoparticles added during manufacture because these nanoparticles are encapsulated in the matrix of the photovoltaic cell and no longer in their 'free' form. In this case, the problem, if one exists, is more likely to be relevant during the disposal or recycling of these materials.

It is important to note that, under current procedures, it can take up to 15 years for a new testing protocol to be validated before it can gain regulatory acceptance. As there will undoubtedly be a requirement for new tests, it may be necessary to look at

ways to streamline this process e.g. adapting genomics testing techniques used in the pharmaceutical industry to assess toxicological endpoints. It may also be important to consider developing less test dominated approaches to risk assessment.

REACH may have an influence on the speeding up (or otherwise) of the approval of alternatives to existing animal tests, however, this does not address the requirement for new tests for novel materials or the requirement for ways of interpreting certain types of current information.

The RSC would also recommend that the Commission consider the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) opinion on *The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies*.⁸

14. *How can you look at the effects of novel materials as a coherent whole, if they are even more difficult to categorise than nanomaterials?*

By implication novel means previously unknown. It is not possible to put a testing framework in place to take into account all (or many) future unknown effects arising from all future unknown materials. A set of general principles (or questions) can be defined and a requirement that these principles are adhered to or questions addressed can be set. The onus should be on manufacturers and suppliers to provide appropriate evidence that novel materials are reasonably safe for intended uses as well as address the sensible concerns that regulators may have. The key is appropriate monitoring of the use/release of novel materials post marketing. This occurs with chemicals placed on the market for specific uses, either, as with drugs, veterinary products through pharmacovigilance schemes or, as with plant protection products, biocides, and chemicals subject to authorisation under REACH, periodic review of the information available. It may also be helpful to group novel materials on their intended use and properties to permit comparison with known materials and to facilitate read across.

THEME 3: How to manage novel materials in society: governance and regulation

16. *Is REACH the right framework for regulating novel materials and nanotechnologies?*

Novel materials derived from new and existing substances will be subject to REACH. Relevant sections of REACH may have to be amended to deal with the way in which substances are incorporated into novel materials. REACH should be made flexible enough for regulating substances that are found in novel materials. However, the presumption cannot be made that the current regulatory regime will be adequate. The first question will be whether the new use leads to exposure to a novel material. If so, then new hazard data may be required for existing materials which are used in a novel ways, and it should not be assumed that this hazard data can be acquired using currently approved tests. The risk assessment arising from this information needs to be included in a Chemical Safety Report. For example, if a known substance is produced in a nano form, but used in the same way as the bulk material, a question arises as to whether further information regarding safety needs should be produced by the applicant.

In this regard an indication of how these materials can be treated could come from considering alloys. It has been acknowledged under REACH that the properties of the alloy are not the same as the two or more individual chemicals, *i.e.* its physical form is being considered. Conversely, there must be concern over the treatment of polymers under REACH. Currently, monomers are covered by this regulatory framework but polymers are not.

REACH relies on self-certification unless the European Chemicals Agency selects the substance/use for 'Authorisation'. This selection process implies the substance has certain hazard characteristics identified by conventional testing before it enters 'Authorisation'. If quantities of less than 1 tonne (and the substance is not known to possess certain properties) are being used then registration is not required and if quantities of less than 10 tonnes are being used then the information required is very restricted and a chemical safety report (effectively a risk assessment) is not required. It remains uncertain as to how much of the nanotechnology industry will be using less than these quantities and therefore subject to 'Authorisation'.

19. *Is the UK's and EU's research funding sufficient in this area? Is it being delivered in the right way?*

The Council for Science and Technology has recently released the report: *Nanosciences and nanotechnologies: A Review of Government's Progress on its Policy Commitments*.⁹ The RSC recommends this review and its comments on research coordination, research funding methods and research priorities. The bottom line is that more funding needs to be provided and it needs to be focused on specific challenges.

23. *How can an appropriate balance be achieved in the design of regulatory systems to effectively manage uncertainty?*

25. *How would you apply the precautionary principle to the management and regulation of novel materials?*

Question 23 is a key question of this consultation, and should be the subject of a study in its own right. This fundamental question is societal, not scientific, and relates to how decisions can be made concerning what is in the best interests of society, and how society sees the relationship between risk and regulatory systems.

As far as is reasonably practicable, regulatory systems for novel materials need to safeguard human health and protect the environment. In the absence of adequate data and evaluation criteria it is difficult to make this judgement concerning what constitutes 'safe', and hence what constitutes 'acceptable', or what constitutes a sufficient benefit to tolerate a risk (*i.e.* what society deems tolerable on a risk/benefit basis – a 'tolerable' risk). It is important to develop an understanding of what the general public, and key sectors within the general public, mean by 'safe', by 'benefit' and by 'tolerable' risk, and to generate a set of principles for defining what constitutes an acceptable/tolerable level of risk.

The RSC has clear concerns that hazard based approaches and the precautionary principle may be used for the regulatory control of novel materials and new

applications of existing chemicals in situations where a risk based approach would be more suitable. Hazard based approaches using the precautionary principle have the advantage of being easy to apply and administer. However, they can result in the misdirection of effort to mitigate risk because they do not deal with the likelihood of a misdirection concerning the hazard (*i.e.* precautionarily protecting against a ‘hazard’ that isn’t [and hence a risk that is assumed too high]) and therefore continuing an existing risk). Comparative risk assessment should aim to optimise the choice of options for a particular situation, taking into account potential risks to health, wildlife and the environment and societal benefits.

The application of the precautionary principle has to be proportional to the risks involved. By adopting a ‘gate keeping’ approach and a ‘hard’ precautionary approach (the normal fallback position of the regulator when facing an unknown) there is a near certainty that innovation will be stifled through the disproportionately high barriers to introducing the new, and probably less risky, materials.

The RSC holds the view that it is vitally important that regulations aimed at mitigating detrimental environmental and health impacts be based on risk. Novel materials should generally not be subject to restriction on the basis of intrinsic hazard alone as this is not a good measure of the actual threat posed. Risk is a better measure as it is based upon the likelihood that an intrinsic hazard associated with a material will cause actual harm.

A balance needs to be found between the benefits of novel materials to society and the risks they pose. It is not possible to eliminate all risk. The RSC is concerned that the normally overly risk adverse nature of society is increasingly leading to risk adverse regulatory systems. This results in regulations inhibiting innovation.

¹ <http://www.rsc.org/ScienceAndTechnology/Policy/Documents/RCEPstudyResponse.asp>

² http://www.ornl.gov/info/ornlreview/v39_1_06/article18.shtml

³ <http://www.oxonica.com/>

⁴ <http://www.suschem.org/>

⁵ <http://www.nanotec.org.uk/finalReport.htm>

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<http://www.rsc.org/ScienceAndTechnology/Policy/Documents/MaterialsforNuclearWastemanagement.asp>

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<http://www.rsc.org/ScienceAndTechnology/Policy/Documents/Renewableenergygenerationtechnologies.asp>

⁸ http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_003.pdf

⁹ http://www.cst.gov.uk/cst/news/Files/nano_review.pdf