

THE ENVIRONMENTAL EFFECTS OF NOVEL MATERIALS AND APPLICATIONS

Executive Summary

1. The Royal Commission should use a broad definition of ‘novel material’ in their study, which incorporates old technological products formulated in a new way.
2. Given the development of a global economy there is now greater international scope for potential environmental impact of novel materials, across the whole lifecycle of product development, from manufacture to disposal and recycling.
3. Regulation needs to encompass biological, ecological and environmental impacts of materials as they move through the food chain . Inevitably, any testing will not provide definitive proof that a material is ‘safe’ but it will increase the confidence that a material is so.
4. There is a need to learn from the lessons of the past , and to develop a more rapid assessment and identification of problems when they arise so that solutions can be addressed as early as possible.

Background

5. The Royal Society of Edinburgh (RSE) is pleased to respond to the Royal Commission on Environmental Pollution study into novel materials and applications. These comments have been compiled with the assistance of a number of expert Fellows of the RSE, under the direction of the Vice-President, Professor John Mavor.
6. Dealing with hazards of new materials or new forms and uses of old materials has been an ongoing activity for over two centuries. Chemical atmospheric and ground pollution from the early alkali industry, smog from open fires and industrial power generation, acid rain, coal dust, asbestos inhalation have, *inter alia*, all been serious problems which have rightly been successfully addressed by legislation. The international scope of potential environmental impact of novel materials is now greater than ever with a lot of electronic waste now ended up in developing countries with little safeguards over its handling and disposal.
7. The specific questions raised by the consultation paper are addressed below.

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 the study?

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?

8. A 'Novel Material' is a material only relatively recently described or introduced into society whose chemistry or physical form is known but whose uses, hazards and further fabrication are still not fully explored. In this context, new should not only consider new technological products, but old technological products formulated in a new way, for example the use of phthalate plasticisers to soften PVC. Over time, items will continually be moving out of this category as these matters are resolved. Nanotechnology, as such, has been with us for a long time in the form of surface and colloid science. Paints are probably the oldest and most widely used example of nanotechnology as it includes an infinity of materials; organic, inorganic, metallic in a wide range of forms including micro- and nano-dispersions which may release active ingredients becoming pollutants, for example with marine paints. Their application to surfaces usually involves the formation of films by evaporating off of solvent and the well established trend towards water as a volatile carrier to reduce toxic and fire risks. The industry handles toxic materials, a common example of which is the use of isocyanates. Industrial paint manufacturing and applications are covered by current legislation and the industry could well serve as a model both of how to operate nanotechnology safely as well as a history of the development of appropriate legislation without the stifling of innovation.
9. Primary classification would be both by their chemistry and by their physical form, with secondary sub-classifications by specific features, such as built-in self degradation; degrees of stability; by size of smallest components; and by electrical, mechanical and optical properties. Two examples of this would be 'soft materials' and 'polymeric composites'. The science of soft materials is becoming increasingly established, for example with the development of hydrogels which are water swollen polymers which are finding major uses in agricultural, biomedical, pharmaceutical and sanitary products. In particular their use in babies disposable nappies now constitute a large use with its own disposal and pollution problems while their application as soft contact lenses guarantee their intimate contact with millions of human eyes every day. They are classified as "devices" and governed by licence via the Medicines and Healthcare products Regulatory Agency (MHRA). Polymer/fibre composites include glass fibre reinforced minesweepers, carbon fibre reinforced planes, golf clubs and pole vaulting poles and will in due course present a disposal problem.
10. All materials should be considered if they meet the definition above but especial consideration should be given to those materials for which there are *a priori* reasons to suspect possible hazard. Such materials include those containing poisonous elements or compounds; nanofeatured surfaces and degrading nanosurfaces that may possibly contain or trap bacteria or viruses; and those where a closely related product has already been shown to have possible or real hazards. In addition, consideration should be given to nanoparticles, especially in

the size range below 30nm; nanocomposites and 3D nanostructures (especially those with voids); and microstructures close to the nano-micro boundary.

What sort of materials and technologies are being developed – over the next 2, 5 and 10 years?

11. A range of materials are likely to be developed over the next 10 years. For example, materials which have ordered 3D structure; surfaces with ordered nanofeatures; and techniques for replicating large areas of ordered nanofeatures . In addition, there is interest in soft materials based on polymers for electronic applications, and other carbon nano-tube composites for mechanical engineering applications. There is also interest in developing new biomimetic and materials based on nature's method of producing materials.

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

12. Novel materials can impact on resource depletion when rare elements are being used in the making of, or as part of, the final product.

Are issues of reuse and recycling considered when developing novel materials?

13. The re-use and recycling component of novel materials is often very poorly thought out. However, with increasing public interest in this issue, novel products are now being developed to specifically appeal to the environmentally conscious, for example products that can be recycled or biodegraded. Nevertheless, the recycling of many plastics is highly problematic due to toxic metals used in their formulation, as will the recycling of devices with radioactive materials, such as smoke detectors. Novel materials may also require special labelling, and if degradation or recycling process generate nanoparticles, special procedures should be in place to advise staff.
14. In the area of rechargeable lithium batteries , the materials being investigated for future applications are typically based on silicon, manganese or iron oxides, where the elements involved are known to be relatively environmentally benign. Nevertheless the forms of these materials have to be new, by definition and often they will be nanostructured materials. Production of rechargeable lithium batteries in 2006 reached 2 billion, with each cell containing typically 10 to 20 grams of materials.

Theme 2: Environmental and health impacts of novel materials

What are the most important impacts that novel materials could potentially have on the environment and human health?

15. Positive impacts of novel materials can be found in a range of applications from improved delivery of medicines that can target areas in the body to improved diagnostic methods. They have also led to better regulations for preventing hazards to the human population from existing and future products, and have produced stronger materials for industry and construction, as well as materials with internal markers of impending failure. Improved fabrication methods are

producing less waste product and improved speed of fabrication and very high efficiency light sources are reducing energy consumption. Special surfaces, such as mimetics of dolphin skin, are also being created for low drag uses, for example on ships, aeroplanes and 'self-cleaning' surfaces, and new energy materials, for example in batteries and for hydrogen storage, are leading to a step change in energy storage and conversion, helping to combating excessive CO₂ emissions and Global Warming. New materials such as hydrogels can be, and are being, developed for clearing contaminated land, reversal of desertification and for economy in the use of water.

16. Novel materials have the potential to have a negative impact on biological systems and on whole ecosystems, as well as on the earth's physical environment itself. For example, chlorofluorocarbons have depleted the earth's ozone layer, and CO₂ emissions are driving global warming. Negative impacts are being caused by diseases due to particle absorption, for example cancers, lysosomal disease, and other diseases caused by changes in gene expression. In this context, materials used in medical implants could be degraded through wear and tear, resulting in fine materials such as titanium, entering the body through phagocytosis.
17. There can also be risks of enhanced fire or explosion from powders, and in particular from nanoparticles, in large quantities and many novel compounds have an over reliance on toxic elements. Unlike most organic compounds, metals once in the waste stream cause considerable pollution that will persist for decades, or centuries. Novel formulations, or synthesis of new compounds from these elements, may have severe environmental consequences. One example of this is the use of platinum compounds in cancer treatment. Platinum is normally considered a highly inert and safe chemical, yet Pt (VI) compounds can be synthesised that are highly toxic and persistent and have found use in chemotherapy. The waste streams of this practice were not considered and led to contamination of sewage streams emanating from hospitals carrying high burdens of this potent Pt formulation.

What are the main mechanisms and pathways for those impacts?

18. The main physical mechanisms of these impacts are through the use of quantum effects; improved bonding of similar and dis-similar materials; and through non-isotropic materials with different physical or chemical properties in one or more dimensions.
19. The life cycle pathway impact of novel materials can occur from manufacture, disposal or accidental fate. For example, dioxins can be produced during PVC manufacture, and can be often involved in burning – either in homes (fire places or bonfires), incineration or large scale warehouse fires – releasing dioxins, (and metal(oids) used in formulation) into the environment. Particle emissions from engineering manufacturing processes can result in the emission of gases from electrolyte solutions and the appearance of hexavalent chromium in spent electrolyte solutions which has to be disposed of as a sludge. The livestock painkiller diclofenac, which is harmless to cattle, has been killing griffon vultures in India and Nepal, which feed on dead cattle.

How do we begin to conceptualise environmental impacts when we are in such unknown territory?

20. In order to conceptualise environmental impact, the main approach is a biological and biomedical one, in terms of the route(s) by which the materials may interact with cells, however it will be important to remain vigilant to ecological and environmental impacts, as they move through the food chain. Questions that can be asked are: How, if at all, can the materials encounter cells? For instance, lungs and airways, eyes, skin penetration and entry (or not) into blood system, gut and genitourinary routes. The more routes and the more general the entry, the greater the potential hazard. Impacts can also be assessed by considering whether the materials either directly, or by virtue of their wear or decomposition, generate small enough particles to enter the cells by phagocytosis (endocytosis). If they do, then what are their final locations - nuclear, phagolysosomes, or mitochondria? Phagolysosomal locations are probably rather less serious than others, however, findings that gene expression can be altered by such encounters suggests there might be hazards which have yet to be seen.

Are current testing protocols 'fit for purpose' to test the potential environmental and health impacts of novel materials? If not, what needs to be developed or are there other strategies needed to address this issue?

21. Present testing systems are too limited and test systems too confined to one cell type or mechanism, and long-term exposure tests are inadequate. However, it is now possible to model and predict toxicology of chemical structures in advance, which could then flag up those that might be problematic for further testing through a tiered assessment of cell biology tests. These need to include tests for chromosomal defect generation, apoptosis, free oxygen radical generation, abnormalities of adhesion and cell movement, and operation of the immune and inflammatory systems. Inevitably, such testing could not provide definitive proof that a material was 'safe' but it would increase the confidence that a material was so.

22. Overall, there is a need to learn from the lessons of the past, and to develop a more rapid assessment and identification of problems so that solutions can be addressed as early as possible. There should, however, be differentiation between the requirements for the development of commercial products and the development and use of novel materials for research purposes, within a health and safety regulated laboratory.

Are the full life cycle impacts of novel materials being considered in terms of their potential effects on the environment and human health?

23. No, and this is a considerable weakness. Regulation and inspection needs to be instigated to ensure that a product is safe throughout its entire lifespan. Full lifecycle costs should be built into the product costs and manufactures, manufacturer federations or manufactures in hand with local/national government should ensure safe recycling of hazardous components.

Theme 3: how to manage novel materials in society: governance and regulation

Are the regulations which affect novel materials fit for purpose? Is existing legislation sufficient to deal with potential problems that could arise during the different stages of the novel material's life cycle, i.e. manufacture, use and disposal?

24. We believe the existing legislation is not yet sufficient to deal with the potential problems arising from novel materials, but that existing regulations could be modified to address the new challenges of these materials. More has to be done on financial penalties for poor practise, and lifecycle regulations need to be developed and enforced.

Is the UK, EU and global science and knowledge base sufficient to support current legislation frameworks and any future regulation? Where are the gaps and what are the research priorities?

25. The science and knowledge base is potentially sufficient to support current legislation frameworks but the process(es) seem to have been driven by actual incidents and a simplistic view of the science involved. More research and knowledge on events at the cellular level is needed to help support legislation.

Can novel materials and technologies be effectively governed and regulated if it is not possible to obtain exposure data before products containing novel materials are produced and made available to consumers?

26. Fairly effective control could be instigated if a standard testing procedure were mandatory before extensive production and marketing. As time went by, the procedure would be modified by experience and should become better and better. Consideration could also be given to the wider use of the 'Yellow Card' system for medicines. This has allowed patients and healthcare professionals to report suspected side effects of drugs to the MHRA.

What are the implications for liability when problems arise even if procedures are properly followed in good faith: who should bear responsibility and what issues arise for insurance and redress?

27. The companies making the product should have liability for problems; unless the regulatory system has failed and then the government should be liable.

Additional Information

28. In responding to this consultation the Society would like to like to draw attention to the following Royal Society of Edinburgh responses which are of relevance to this subject: European Commission's Chemicals White Paper (April 2001) and Royal Commission study on the long-term effects of chemicals on the environment (February 2002). Copies of these can be found on the RSE website (www.royalsoced.org.uk).

29. Any enquiries about this submission should be addressed to the RSE's Research Officer, Dr Marc Rands (email: evidenceadvice@royalsoced.org.uk).